EXHIBIT D
Part 2

Original Research

Symptom Resolution After Operative Management of Complications From Transvaginal Mesh

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OBJECTIVE: Complications from transvaginal mesh placed for prolapse often require operative management. The aim of this study is to describe the outcomes of vaginal mesh removal.

METHODS: A retrospective review of all patients having surgery by the urogynecology group in the department of obstetrics and gynecology at our institution for a complication of transvaginal mesh placed for prolapse was performed. Demographics, presenting symptoms, surgical procedures, and postoperative symptoms were abstracted. Comparative statistics were performed using the χ^2 or Fisher's exact test with significance at $P<.05$.

RESULTS: Between January 2008 and April 2012, 90 patients had surgery for complications related to vaginal mesh and 84 had follow-up data. The most common presenting signs and symptoms were: mesh exposure, 62% (n=56); pain, 64% (n=58); and dyspareunia, 48% (n=43). During operative management, mesh erosion was encountered unexpectedly in a second area of the vagina in 5% (n=4), in the bladder in 1% (n=1), and in the bowel in 2% (n=2). After vaginal mesh removal, 51% (n=43) had resolution of all presenting symptoms. Mesh exposure was treated successfully in 95% of patients, whereas pain was only successfully treated in 51% of patients.

CONCLUSION: Removal of vaginal mesh is helpful in relieving symptoms of presentation. Patients can be reassured that exposed mesh can almost always be successfully managed surgically, but pain and dyspareunia are only resolved completely in half of patients.

(Obstet Gynecol 2014;123:134–9)
DOI: 10.1097/AOG.0000000000000042

LEVEL OF EVIDENCE: III

Complications from permanent synthetic mesh used in vaginal prolapse repair have been well documented.[1–4] A mesh exposure or infection can sometimes be treated with conservative measures such as topical estrogen cream or antibiotics alone. Pain or dyspareunia after vaginal mesh surgery can sometimes resolve on its own or be successfully treated with physical therapy or other treatments. However, surgical removal of transvaginal mesh may be recommended as a result of these and other symptoms. With the recent U.S. Food and Drug Administration warning regarding transvaginal mesh and the increase in litigation, more patients may be interested in removal of mesh than other more conservative treatments.[5]

There have been many studies published reporting on the rate of complications after placement of vaginal mesh. However, there have been fewer studies published on outcomes after surgical removal of transvaginal mesh. Therefore, there have been little data to guide the physician when counseling patients about expected outcomes after removal of the vaginal mesh. The aim of this study is to present a description of operative findings, an analysis of our patients' experience, and the outcomes of vaginal mesh removal.

MATERIALS AND METHODS

This is a retrospective chart review of all patients undergoing removal of vaginal mesh by the urogynecologists at our institution between January 2008 and April 2012. Approval was obtained by the University of

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Financial Disclosure
Dr. Delancey is a consultant for American Medical Systems. The other authors did not report any potential conflicts of interest.

ISSN: 0029-7844/14

Michigan institutional review board (HUM00038668). Patients who had mesh removal were identified by Current Procedural Terminology codes. Those patients who had removal of a midurethral sling only or sacrocolpopexy grafts were excluded, leaving only those patients undergoing removal of vaginally placed mesh used to treat prolapse. The operative report from the original mesh placement surgery was obtained from the outside institutions and reviewed as well as reports from any previous mesh-removal procedures. A chart review was performed and demographics, medical and surgical histories, and presenting signs and symptoms were recorded as well as postoperative symptoms.

Patients were classified as having a chronic pain condition if they had a history of chronic pelvic pain, endometriosis, interstitial cystitis, irritable bowel syndrome, fibromyalgia, or vulvodynia that predated mesh placement. If a patient reported pain as a presenting symptom before mesh removal, the improvement after mesh removal was categorized as little to no improvement, moderate improvement, or significant improvement or resolution using the patient's description of improvement. The improvement after mesh removal was categorized as little to none if the phrase used was, for example, "no better," "pain is not improved," "slightly better." Examples of phrases for which a patient was categorized as moderate improvement include "50% better," "somewhat improved," and "still with some pain." Examples of phrases for which a patient was categorized as significant improvement or pain resolution include "much better," "the pain is almost gone" and "80% improvement." In instances in which phrases used fell into more than one category, the chart abstractors judged which predominated.

The operative report from the mesh-removal procedure at our institution was reviewed. Details of the procedure were recorded including the vaginal compartment from which mesh was removed and whether the mesh removal was "partial" or "all vaginally accessible." A mesh removal was categorized as "all vaginally accessible" if all mesh was removed to the level of the pelvic sidewall, with or without removal of the mesh arms, and "partial" if less mesh was removed.

Mesh excision was performed by making an incision in the vaginal epithelium and sharply dissecting the mesh from the overlying epithelium and underlying connective tissue. The mesh was divided in the midline, the dissection carried as far from the midline as desired, and the mesh removed. Typically, if the procedure was performed for mesh exposure and no other bothersome symptoms, only the mesh involved in the exposure was removed. If the presenting symptom was pain or dyspareunia, or if the patient desired complete mesh removal, as much mesh was removed as possible. Once the mesh was removed, a concomitant prolapse repair or anti-incontinence procedure was performed if needed. The vaginal epithelium was closed in a tension-free manner.

Descriptive statistics were performed. Comparative analyses were done using the χ^2 test or Fisher's exact test with $P<.05$ as significant.

RESULTS

The number of mesh-removal procedures performed at our institution over the 5-year period was reviewed, and the number of procedures performed per year continues to increase (Fig. 1). During the study interval, 108 patients were identified who had a mesh-removal procedure performed by the urogynecologists at our institution. All of the records were reviewed, and 18 patients were excluded as a result of excision of a midurethral sling only (n=10) or sacrocolpopexy mesh (n=8). Demographics of the remaining 90 patients are shown in Table 1 as well as surgical procedures performed before presentation to our office. Of the 90 patients, 39 (43%) had prior mesh-removal procedures: most had one or two prior mesh-removal procedures, but three patients had three or more removal procedures including one patient who had six prior mesh-removal procedures.

Table 2 shows the vaginal compartment from which mesh was removed, the specific brand of mesh removed, and the concomitant procedures performed at the time of mesh removal. In addition to those listed, three patients had rectovaginal fistula repairs and one patient had a vaginoplasty with a full-thickness skin graft for vaginal stenosis. The median length of time between mesh placement and mesh removal was 24 months (range 5–96 months).

Findings at the time of surgery revealed that in 63 of the 90 patients (70%), the mesh was not found to be

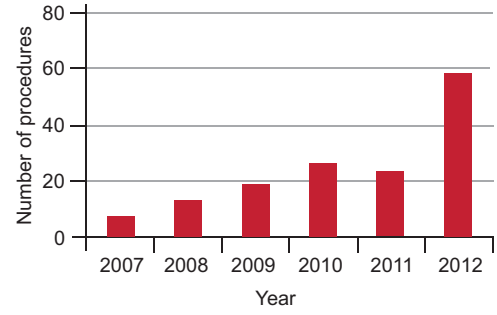

Fig. 1. Mesh-removal procedures performed in the urogynecology division at a tertiary referral center.

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Table 1. Demographic Characteristics and Previous Procedures

Characteristic	N=90
Age (y)	58±11
Parity	3 (0–10)
BMI (kg/m^2)	29.5±11
Current smoker	19 (21)
Postmenopausal without daily hormone therapy	58 (64)
Sexually active	55 (61)
Surgeries before initial mesh placement	
Hysterectomy	52 (58)
Anterior colporrhaphy or bladder suspension	15 (17)
Posterior colporrhaphy	9 (10)
Apical suspension or paravaginal defect repair	3 (3)
Anti-incontinence procedure	11 (12)
No. of prior mesh revision procedures	
1	28 (31)
2	8 (9)
3 or more	3 (3)

BMI, body mass index.
Data are mean±standard deviation (age and BMI), median (range [parity]) or n (%).

Table 2. Procedures Performed at the Time of Mesh Removal

Procedure	n (%)
Compartment of mesh removal	
Removed anterior mesh only	50 (56)
Removed posterior mesh only	19 (21)
Removed anterior and posterior mesh	21 (23)
Specific mesh removed*	
Perigee	22 (24)
Apogee	18 (20)
Anterior Prolift	17 (19)
Anterior Avaulta	15 (17)
Posterior Prolift	11 (12)
Posterior Avaulta	10 (11)
Elevate	6 (7)
Gynemesh	6 (7)
Anterior Pinnacle	5 (6)
Uphold	4 (4)
Avaulta	3 (3)
Anterior unspecified biologic graft	3 (3)
Posterior unspecified biologic graft	3 (3)
Posterior Pinnacle	2 (2)
Proxima	1 (1)
Pelvisoft	1 (1)
Unknown	6 (7)
Concomitant procedures	
Concomitant hysterectomy	5 (6)
Concomitant prolapse repair	50 (56)
Concomitant anti-incontinence procedure	9 (10)

* The risk of complication from specific mesh kits cannot be extrapolated from these data because this is a case series.

lying flat or tension-free at the time of mesh removal. Descriptions of the mesh in the operative report from our mesh-removal procedure include: bunched, rolled, tight-band, wadded, gathered, or taut. Many different meshes were removed as seen in Table 2.

The most common presenting signs and symptoms were: pelvic or vaginal pain, 64% (n=58); mesh exposure, 62% (n=56); and a bulge sensation, 30% (n=27) with most patients reporting more than one symptom (see Fig. 2). Another common presenting symptom was dyspareunia, reported by 48% (n=43). Other presenting symptoms include recurrent infection, 9% (n=8); stress urinary incontinence, 28% (n=25); rectovaginal fistula, 3% (n=3); and defecatory dysfunction, 35% (n=32). Of the 56 patients who presented with mesh exposure, 26 had vaginal bleeding or bothersome vaginal discharge, 20 had pain or dyspareunia, four were bothered by the exposure with no specific symptom mentioned, one had recurrent vaginal infections, four had recurrent prolapse with an asymptomatic exposure, and one had stress urinary incontinence with an asymptomatic exposure.

Operative reports for the initial mesh placement surgery were reviewed before mesh removal and the expected location of the mesh noted. During the mesh-removal procedure, mesh was encountered unexpectedly in a second area of the vagina in 5% (n=4); for example, an operative report described mesh only in the anterior vaginal wall, but examination under anesthesia revealed mesh in the posterior vaginal wall as well. Mesh was encountered in the bladder in 1% (n=1) and in the bowel in 2% (n=2). The presenting symptoms most bothersome to the

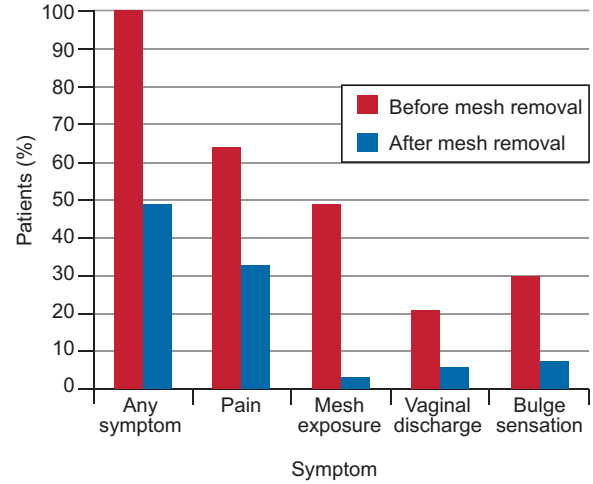

Fig. 2. Symptoms before and after mesh removal.
Crosby. Symptom Resolution After Mesh Complications. Obstet Gynecol 2014.

patient with mesh in the bladder were pain, urinary incontinence, and recurrent urinary tract infection. One patient found to have mesh involving the bowel reported recurrent prolapse and pain and the other patient reported pain and dyspareunia. Seven patients required reoperation after mesh removal at our institution. One patient was found to have mesh in the bladder that required subsequent cystoscopic laser removal. Two patients had an autologous fascia pubovaginal sling placed after the mesh-removal procedure: one had recurrent urinary incontinence after a portion of a synthetic midurethral sling was removed and the other had a planned staged procedure for removal of her mesh and then treatment of her incontinence. Four patients (5%) required an additional vaginal mesh-removal procedure.

Follow-up data were available for 84 of the 90 patients. The median follow-up length with interquartile range was 4 (2, 11.5) months. However, 29 of the 84 patients had 2-month follow-up, 29 had up to 6 months follow-up, eight had up to 1-year follow-up, and 18 had follow-up beyond 1 year. After vaginal mesh removal, 51% (n=43) had resolution of all presenting symptoms. Of the patients who presented with mesh exposure, 95% were treated successfully and did not require any further treatment. Persistent symptoms were reported by 51% of those who presented with pain (Fig. 2). The proportion of patients with each symptom before and after mesh removal were compared and there was a significant decrease in the proportion with each symptom after mesh removal ($P<.01$). Of the 43 patients who reported dyspareunia, 30% reported persistent dyspareunia at most recent follow-up.

Improvement in pain symptoms was analyzed as a result of the relatively high persistence of symptoms after surgery (see Fig. 3). There were 16 women (25%) who carried a preoperative diagnosis of a chronic pain condition and all presented with pain. Of these 16 women, six had little or no improvement in pain compared with five of the 39 women who presented with pain and did not have a chronic pain condition (37% compared with 13%, $P=.06$). Patients who had removal of all vaginally accessible mesh were not more likely to have a significant improvement in pain compared with those who had partial mesh removal (58.1% compared with 70.1%, $P=.4$). The number of prior mesh-removal procedures was also not associated with pain resolution. There was one patient who had de novo pain after mesh removal. She had an autologous fascia pubovaginal sling placed at the time of mesh removal and had persistent pain at the Pfannenstiel incision site at last follow-up.

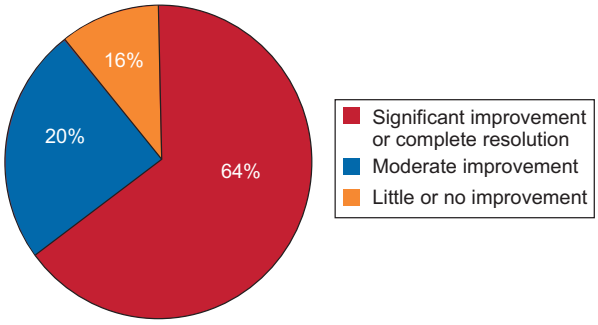

Fig. 3. Change in pain after mesh removal.
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DISCUSSION

In this study, complete resolution of all symptoms including vaginal discharge, bleeding, mesh exposure, and pain was achieved for approximately 50% of patients on whom follow-up was available. The symptom most difficult to relieve with surgical management was pain. Significant improvement or complete resolution of pain was achieved in 64% of patients, whereas 36% of patients had moderate or no improvement in pain after mesh removal.

The persistence of pain after mesh removal is consistent with several other series in the literature.[2,6–10] The reported rate at which pain is relieved with surgical management in these prior reports ranges from 50% to 78% but little is known about risk factors for persistent pain. In our series, we found that patients with a chronic pain disorder were almost three times more likely to have continued pain after mesh removal than those without a chronic pain disorder (37% compared with 13%, $P=.06$). We hypothesize that patients with pre-existing pain syndromes have underlying pathophysiology predisposing them to persistent pain, even after mesh has been removed. In general, our approach is to manage expectations by explaining that mesh removal may be one component of a broader treatment plan, which may also include other modalities such as neuropathic pain medications, trigger point injections, and physical therapy.

Some patients who present with pain have a finding on examination that may explain their symptoms such as mesh that is bunched or folded or have an obvious mesh contracture. These women often have a single point or focal area that is painful on examination. Pain relief after mesh removal has been reported in up to 100% of women with obvious mesh contracture.[9] However, in other patients, we found no anatomic abnormality on examination; the vagina was supple and the mesh seemed to be lying flat and

tension-free, and yet they have had considerable pain since the mesh was placed. It is now our practice to perform removal of all vaginally accessible mesh on those without focal tenderness or clear bunching or folding of mesh and to perform a partial mesh-removal procedure on those with focal tenderness or other finding such as one tender arm of mesh. However, there are instances in which removal of all vaginally accessible mesh was the goal, but a partial removal was done as a result of the risk of increased bleeding or damage to the bladder or bowel during the dissection. At times, one must consider the risk of an intraoperative complication during aggressive removal of all vaginally accessible mesh, because it is not known whether this yields better outcomes than partial removal.

Firoozi et al[11] reported on the operative management of complications from vaginal mesh placed for prolapse in a series of 23 patients. In that series, 11 (48%) patients presented with pain or dyspareunia and all but one patient had resolution of the pain or dyspareunia at last follow-up. The mesh removal technique for patients with pain as described in that study is similar to our practice. The median length of time between mesh placement and mesh removal in our study was 24 months. It was not reported in the Firoozi et al study, so it is possible that those patients had a shorter latency to mesh removal, which may affect the risk of persistent pain. It may also be related to the smaller size of that study or the specific mesh kits that were removed. The mesh removed in that study was from one of four types of mesh kits (Prolift, Apogee, Perigee, or Avaulta). In contrast, there were 10 different mesh kits in our series. However, it is important to note that any statement about the risk of persistent pain among different mesh kits should not be extrapolated from a case series such as this, because it is impossible to know the number of patients who received each kit and did not have problems. The role of our study is to provide information on symptom resolution in those women who require surgery for these problems.

Although 30% of our patients had persistent dyspareunia after mesh removal, many patients had not yet had intercourse at the time of last follow-up. Furthermore, it is not known whether this and other symptoms are likely to resolve with time.

This study describes the degree to which symptoms resolve in the short term in one of the largest series of prolapse mesh removal cases reported. There are, however, several limitations to consider in interpreting the results of our study. As a result of its retrospective design, intraoperative data and outcomes were not collected in a standardized fashion and a validated pain assessment was not performed. It is a custom, however, at our institution to have a very detailed operative findings section of the operative note, including, for example, details of the location of mesh exposure, presence or absence of banding and its location, and a detailed description of any prolapse present. In addition, a focus of our postoperative visits is to assess success or failure of symptom resolution. The International Urogynecological Association/International Continence Society graft complication classification system was published during the time when this cohort of patients had surgery and collecting information required by this classification system was not a part of our practice.[12] Furthermore, as a tertiary referral center, it is difficult to obtain some components of the International Urogynecological Association/International Continence Society classification system, for example, T (time from mesh placement to initial clinical diagnosis of a complication). Many patients had a concomitant prolapse repair at the time of mesh removal and it is unclear how much this contributes to their symptom burden postoperatively. A quality-of-life assessment was not performed and the metric used for pain improvement was based at times on subjective phrases in the medical record. Because it is a case series, we cannot comment on the frequency or risk factors of complications of individual vaginal mesh kits. Similarly, because we do not place transvaginal mesh for prolapse, we cannot make any comparative statements about our cohort of patients and those who have transvaginal mesh placed and do not require additional treatment.

There are myriad clinical problems resulting from transvaginal mesh that clinicians must manage with little data or experience to guide them. The persistence of pain in 30% of patients suggests that treatment of persistent pain may be among the most difficult. In our experience, issues that may have an effect on outcomes of mesh removal include partial compared with complete removal and patient willingness and ability (financial, logistical) to pursue physical therapy, trigger point medications, and to tolerate neuropathic pain medications postoperatively. However, we were unable to analyze these variables as a result of the size of the study. This analysis suggests that patients with a history of chronic pain diagnoses may not be ideal candidates for the use of synthetic materials or implants and are at a higher risk for persistent pain after mesh removal.

In summary, there are many symptoms well treated with mesh excision. Vaginal bleeding and discharge, erosion, and urinary symptoms are relieved

in the overwhelming majority. This analysis has demonstrated to us that we need to be careful to establish realistic patient expectations with respect to immediate and longer-term pain relief. It is our hope that with additional care, including the aforementioned treatments, our patients will experience at least adequate or complete relief of pain.

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Changed Women: The Long-Term Impact of Vaginal Mesh Complications

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Objectives: The aim of this study was to describe how women experience vaginal mesh complications after optimized tertiary care level treatment.

Methods: We conducted telephone interviews in 2012 with women at least 6 months after presentation to our tertiary care clinic between 2006 and 2011 for complications related to vaginal mesh and transcribed verbatim responses to 2 open-ended questions about their experiences surrounding vaginal mesh complications. We analyzed data using qualitative description with low-inference interpretation in a team-based setting followed by consensus meetings to arrive at descriptive trajectories of their experiences.

Results: Of 111 women, we successfully contacted 88, and 84 agreed to the interview. The mean duration from index mesh surgery to interview was 4.5 years, and the mean duration from presentation to our clinic for complications to the interview was 2.3 years. The effects of mesh complications caused both physical and emotional pain, in addition to the discomfort of the original pelvic floor dysfunction. The women's experiences followed 1 of 3 recovery trajectories. In "cascading health problems," the women experienced a spiral of health problems, anxiety, and desperation. In "settling for a new normal," the women who once considered themselves healthy now believed that they are unhealthy and worked to adjust to their degraded health status. In "returning to health," the women described a return to health. The women still symptomatic discharged from tertiary care clinic expressed hopelessness and abandonment.

Conclusions: Concomitant with ongoing research to improve the safety of vaginal mesh procedures, there must be dedicated efforts to develop and study a range of therapies for holistically treating women with mesh complications.

Key Words: pelvic organ prolapse, stress urinary incontinence, mesh complication, vaginal mesh, qualitative analysis

(*Female Pelvic Med Reconstr Surg* 2014;20: 131–136)

Pelvic organ prolapse (POP) and stress urinary incontinence are both common disorders among women, with up to 50% of the general female population developing POP and 30% developing stress urinary incontinence.[1,2] As many as 19% of women will undergo surgery for POP by the age of 80 years.[3] High recurrence rates associated with native tissue repairs for these disorders have increased the popularity of synthetic mesh procedures. Their prevalence has been followed by an increased incidence of complications specific to this repair method, as stressed in the 2008 Food and Drug Administration Public Health Notification[4] and 2011 Update.[5] Common complications include mesh exposure and contraction, with mesh exposure occurring in 10.3% of patients.[6] Complications from vaginal mesh have a significant impact on patients' quality of life. In a review of 2 tertiary institutions, 45% of patients presenting for mesh complications reported pelvic pain and 72% reported dyspareunia.[7]

Advances in the care of POP in the last century have become increasingly specialized and attuned to surgical options. In parallel with efforts to cure the physical symptoms of women with POP is a humanistic call to attend to women's experiences as they undergo illness and treatment. Humanizing health care is not a call to seek complementary or alternative care, nor is it a rejection of the medical paradigm. Rather, humanizing health care is a movement that highlights the esthetic of care and communication with providers in tandem with the science of care.[8,9] Qualitative research describes women's experiences throughout the health-illness trajectory. The purpose of this study was to describe how women experience vaginal mesh complications after optimized treatment by tertiary care level physicians, a mean of 2.3 years after treatment and 4.5 years after mesh placement.

MATERIALS AND METHODS

Participants in this qualitative research were women who presented to our urogynecology division for complications related to vaginal mesh between January 1, 2006, and December 31, 2011. They were identified by the following diagnostic codes: mesh erosion, 939.2; mechanical complication of graft, 996.39; pain due to genitourinary device/implant, 996.76; infection of genitourinary device/implant/graft, 996.65; unknown foreign body, 939.0; mesh excision vaginal, 57295; and mesh excision abdominal, 57296. Of these, only the participants whose initial surgery included a vaginal mesh kit for POP, an abdominal sacrocolpopexy with mesh for POP, or a suburethral mesh sling for urinary incontinence were included. Women presenting with complications from nonsynthetic grafts and from sutures were excluded from this study. We did not consider recurrent POP and/or incontinence as mesh complications.

After evaluation by 1 of 3 urogynecologists, the women underwent various types of treatments designed to optimize their presenting symptoms to the best degree possible; symptoms, therapies, and quantitative outcomes of treatments are summarized in a companion article.[10] For the most part, therapies were administered by urogynecologic surgeons, a pelvic pain specialist, and women's health physical therapists.

One hundred eleven women met the study criteria and were sent letters with a description of our project, notification that we would contact them, and options to either decline participation

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Reprints are not available.

The authors have declared they have no conflicts of interest.

DOI: 10.1097/SPV.0000000000000083

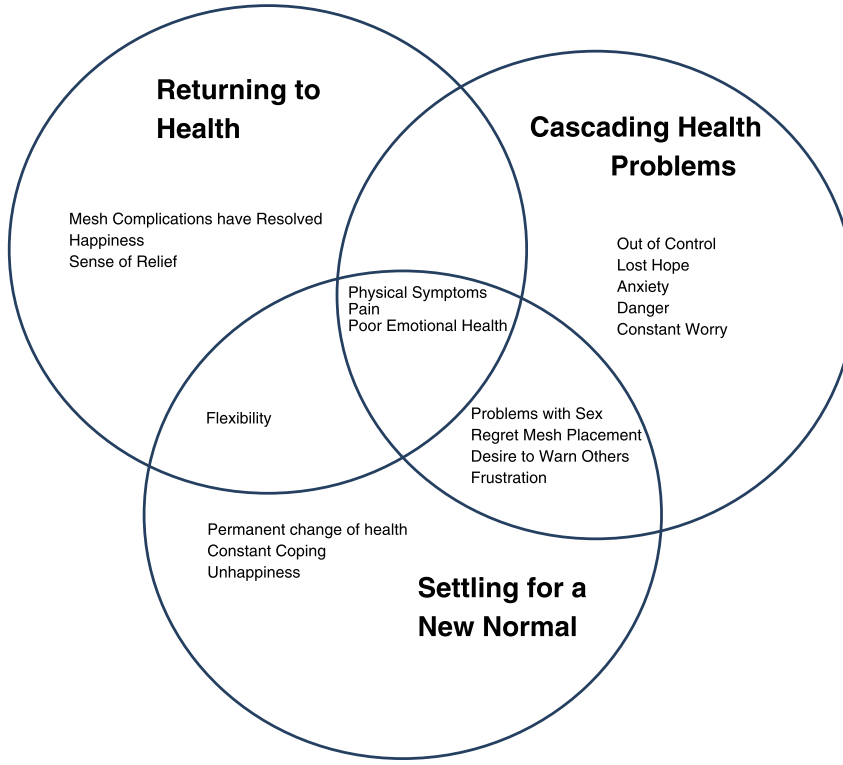

FIGURE 1. Relationship of the major codes to each of the 3 trajectories and areas of experiential overlap between the trajectories.

or request a mail-in survey instead of the telephone interview. In addition to validated measures described in our companion article, the interviewer asked 2 open-ended questions: (1) What can we do to improve our clinic to help women in the future with problems related to vaginal mesh? and (2) Is there anything else you'd like us to know about how your problems related to your initial surgery have affected you?

Two researchers conducted all telephone interviews and transcribed verbatim the women's responses to the open-ended questions. Data were analyzed using qualitative description[11] with low-inference interpretation. The goal of the analysis was to provide a straightforward, unadorned description of women's experiences of mesh complications to humanize the experience as personal, contextual, and embodied. The data were downloaded into an Excel file and coded in a team-based setting, followed by independent coding and subsequent consensus meetings. Two researchers achieved consensus on the meaning, coding, and categorization of each response.

The University of Utah institutional review board reviewed this project before we began any data collection and concluded that it does not meet the definitions of Human Subjects Research according to Federal regulations.

RESULTS

Contact information was incorrect or outdated for 10 women, 1 woman was excluded because of language barrier, 1 was deceased, and 11 women did not respond to contact attempts. Thus, we were able to contact 88 women. Of these, 5 requested the mail-in paper survey (and 2 returned it) and 1 declined participation. Thus, 84 (76.1%) of 111 ultimately provided follow-up information. For these 84 women, the index surgeries in which mesh was placed were midurethral sling (29), vaginal mesh kit for POP (41), abdominal sacrocolpopexy (10), and vaginal mesh kit plus midurethral sling (4). The mean length of time from the index surgery in which vaginal mesh was placed to the interview was 4.5 years, and the time from presentation to our clinic for complications to the interview varied from 209 days to 6.5 years (mean, 2.3 years). For those women who provided qualitative data, the mean age at presentation to our clinic was 54.1 years (range, 30–81 years). Sixty-four women were married or living as married (77.1%), 11 were divorced (13.3%), 6 were widowed (7.2%), and 2 were single (2.4%). Most women (72%) were referred to our clinic by someone other than the original surgeon.

Of the 84 women who were interviewed, 82 responded to question 1 (What can we do to improve our clinic to help women in the future with problems related to vaginal mesh?), and of these, 51 provided enough data to be coded for qualitative analysis to identify trajectories of recovery. Eighty-three women responded to question 2 (Is there anything else you'd like us to know about how your problems related to your initial surgery have affected you?), and of these, 71 provided enough data for qualitative analysis. Examples of data considered insufficient for coding were answers to question 1 such as "nothing" or "I have no complaints" or "you guys are fabulous." An answer of no to question 2 rendered the data noncodeable.

The women described their experience with vaginal mesh related to both their perceptions of the initial mesh placement/subsequent treatment of complications and how such complications have affected their daily lives.

The effects of mesh complications caused both physical and emotional pain, in addition to the discomfort of the original pelvic floor dysfunction. Living with that pain, the women's experiences followed 1 of 3 trajectories: cascading health problems,

settling for a new normal, and returning to health. These paths share some characteristics but remain distinct in the severity and the resolution of the mesh complications in terms of the women's everyday lives. Figure 1 illustrates the relationship of the major codes to each of the 3 trajectories and areas of experiential overlap between the trajectories.

The women with experiences following all 3 trajectories described physical symptoms, such as pain, bleeding/spotting, or discharge. These symptoms, especially pain, were generally described with more severity among the women with cascading health problems and those settling for a new normal.

Cascading Health Problems

Nine women had cascading health problems and felt that their health was out of control. They expressed experiencing a spiral or cascade of health problems attributed to the mesh complication that left them feeling that they had run out of options to regain their health. They felt anxious, discouraged, and desperate as they felt that their health was persistently deteriorating. Their descriptions of their health were emotional and evocative.

The uncertainty of cascading health problems required the women to be vigilant, watching for changes in health status. "This is a very emotional thing. Every time something unusual happens to me, I wonder if it's the mesh. Now I feel like I can't stay out of the hospital. It's very scary." Part of the vigilance was monitoring known complications and constantly wondering whether new problems were related to the mesh.

"I have to constantly think about and worry about infections."

"I was thinking she'd be able to take all the mesh out, but I wonder if the remaining piece is where the pain is. [I'm] still worried about remaining mesh."

Hope for a pain-free, symptom-free future was dampened for the women who had been told by their physicians that little more could be done to alleviate their mesh placement symptoms. Many accepted this and drifted into hopelessness. Others were critical of what they perceived to be the inability or unwillingness of their physician to help them.

"I wish it could be fixed."

"I hope the pain and ache goes away, but I'm told it will likely not, which is depressing but not surprising."

"I wanted someone to tell me they could help me, I was alone and afraid. Elsewhere they were able to do that."

The women's imagery of the mesh emphasized its "otherness" inside their bodies and its unpredictable effects. They envisioned the mesh as a foreign body ruining their health from within.

"Not all [of] the mesh is out so I still have some problems."

"The mesh is balled up and I think it affects my bowel movements."

The women perceived a sense of danger or injury from vaginal mesh. "I felt like a victim and afraid."

"If there was any way you could help educate women in the dangers of surgical mesh…."

Two women captured the severity and the constancy of the pain for the women with cascading health problems: "I hurt all the time, all day, every day. I have not woken up pain-free since the surgery. I don't know if I will ever not have pain again, which is very frustrating." Another added descriptive language, saying that the pain was "awful" and like being "ripped apart from the inside." If the mesh was not removed, she feared that she would endure the ripped-apart feeling for the rest of her life. The buffer of resources the women used to cope with their cascading health problems and the uncertainty of new symptoms was often depleted after months of difficulties related to their complication. The depletion was emotional but also practical. "I've used up all of my sick pay and much of vacation," said 1 woman.

Settling for a New Normal

The women who once considered themselves healthy individuals now believe that they are unhealthy. Thirty-two women followed this trajectory. Their stories were longer than those of the women whose mesh complications had resolved and frequently held more emotion. Their symptoms and complications were static, although for some women, these stable conditions were still unpleasant and relentlessly bothersome. The women settling for a new normal felt that their degraded health status was permanent. Some women had come to peace with this change; others had not. They were all, however, in some stage of adaptation or acceptance to what they perceived to be the new normal.

These women experienced a spoiled identity as a result of mesh complications. They describe a sense of not returning to the state they were in before mesh surgery, which was already a state of coping with a health condition. They experience degraded self-esteem and body image or have lost their sense of femininity.

"It's really diminished my self-esteem. It has diminished my health … I used to consider myself a lovely woman—I don't anymore."

"I'm only about 15% the person I used to be."

"I just never did bounce back to what was normal—as good as I felt when I went in."

"Everything has changed. Really—mentally, physically, emotionally—I am a different person. It's hard. I was a superstar, high-performing person and the mesh just put me down. I misjudged people who have health issues—I used to have no patience. It is the challenge of my life."

The women settling into a new normal health state were adapting to loss of function and altering their lifestyles to accommodate problems related to mesh complications. Some dealt with daily predictable, annoying symptoms. Others coped with a diminished quality of life they directly attributed to mesh complications.

"It has destroyed my life. I cannot drive, I cannot travel, I cannot watch movies, I cannot wear heels; I can't drive my car because it's painful. My life has totally changed."

"I had expected the surgery to make my life better, but it has permanently altered my life in multiple ways … many of them are devastating."

"It's hard to live with this, constantly, especially when I am traveling and have to be constantly changing my pads. It's changed my lifestyle—it's most unpleasant."

"The initial surgery took a year off my life."

"It's almost [begins to choke up] ruined it [my life]."

Some women grew too emotional to discuss how the mesh has impacted their lives.

"[I] can't go into how this has changed my life right now" (said weepily).

"I can't even think about it [how the initial surgery has affected her] because that's when the depression kicks in."

The women settling for a new normal shared many experiences, most notably regret, compromised intimacy, and unhappiness. They frequently mentioned their original mesh surgery or surgeon as part of their personal complication experience. They also expressed feelings that their emotional health had been compromised.

Both the women who are settling for a new normal and those with cascading health problems regretted having mesh placed. They felt as if they did not understand the risks for complication before surgery and would not have gone through

with the surgery if they had. Some blamed the surgeon and did not believe that their physicians fully explained the risks.

"He [the original surgeon] was irresponsible, he did not explain to me any consequences, he was dishonest, he said the surgery would be easy for me, I was so much worse."

"I wish I had never had it done. The doctor who placed it was supposed to be a good doctor, but it really messed things up and made my life miserable for a while."

"I wish I hadn't had the surgery. The mesh was probably the worst thing I've ever done."

"I wish I had never had the mesh surgery on my bladder. I don't think it helped the problem and just created a new problem."

Because of their negative experiences with the mesh, many women felt the need to warn or educate other women against its use. They suggested that physicians use more caution with the product or stop using it altogether.

"I just want help because that doctor—he closed his clinic and moved to [another state]. And he is still doing those surgeries on other women."

"Let everyone know not to get mesh."

"Never have vaginal mesh. You should go to another doctor if they suggest it to you. I hate it; it's not good for anything. Has totally ruined my life."

The women experienced significant problems with sex either for an extended period or persisting until the interview. They found intercourse painful, felt as if their sex life was ruined, were unable to have any sexual relations, or were afraid to try. These issues had a negative impact on the women's relationships.

"It took a big toll on my marriage as we were unable to be intimate for a year and a half."

"I haven't been able to have sex since my surgery. I told her how important my sex life was with my husband but she acted like it didn't matter."

"I've had gentlemen ask me out and I've hesitated because I wouldn't want to face marriage not knowing how that [sex] would be affected, so I avoid it."

"Not being able to have sex is causing my married life to just fall apart. All that testosterone [my husband has] and no release is just … I'm always upset and he is too. It's awful."

The women experienced isolation from people and relationships. They felt frustrated, devastated, and miserable. Some felt as if they were living in their personal hell or nightmare in their new, postmesh "normal" state.

"I feel like I've lost my family."

"I can't imagine anyone was any worse than me. My life was hell for 5 to 6 years."

"I can't function as a woman; I don't feel like a woman. I don't know how I will possibly find a relationship."

The range of experiences in the settling for a new normal trajectory were varied, with some women making modest adjustments to accommodate changes in their physical health and others merely settling into a new and unpleasant state of compromised well-being physically and emotionally.

Returning to Health

Ten women described their experience with vaginal mesh complications as returning to health and a resolution of symptoms and issues. They tended to answer succinctly and did not express significant emotion throughout the interview. Although some women mentioned their initial problems from mesh complications, the responses were focused on their return to health in a broad sense. Minor lingering symptoms persisted for some women, but their overall trajectory of recovery was still positive. The women were no longer concerned with their initial mesh placement and did not discuss the original surgeon. These women are no longer experiencing the symptoms that caused them to seek treatment of mesh complications.

"The repair surgery made everything better. It [the mesh and related problems] had incapacitated me for 2 years. It was horrid before, but so much better [after the mesh removal]."

"I feel 100% better since I had it fixed."

For some women, the benefits of mesh as a treatment of POP outweighed the drawbacks of their complications. If given the chance, these women would make the same decision regarding surgery with vaginal mesh.

"It wasn't that big of a deal. The complication was little and I would do the surgery over again."

Treatment of mesh complications left many women with a sense of relief after a previous state of desperation. This was experienced by the women whose complications resolved as a result of treatment.

"I was desperate when I came there; I was in bad shape. I was thoroughly dissatisfied [with my initial surgery] and it was a relief to find someone who understood and knew what to do … There are no long-term effects."

This sense of relief was also experienced by those whose symptoms had improved with treatment, even if remaining symptoms still detracted from their overall quality of life to some degree. The women worked around mesh complications so as to enjoy life in much the same way as they had before mesh placement. They talked about taking a flexible approach to their lifestyle, sex life, or incontinence management in the process of returning to health.

"I still have some ongoing problems. I am creative and try to adjust and work around the problems, but sexual relations with my partner are not enjoyable a lot of the time."

Some found relief from mesh complications through nonmedical means.

"I went through extensive counseling for my bowel, and that was huge. They [provider of bowel counseling] taught me what to eat, when and how to eat. It kept me from being an invalid—I can actually control it now."

DISCUSSION

We identified 3 trajectories through which women experience vaginal mesh complications: cascading health problems, settling for a new normal, and returning to health. In this sample, a minority of the women interviewed fell into the returning to health trajectory. Most continued to have problematic recovery trajectories, even after a mean of 2.3 years from treatment of the mesh complication and 4.5 years from index surgery.

The women who seek care for mesh complications are already adjusting to a chronic pelvic floor dysfunction that alters body image and personal relationships and changes intimacy practices.[12] Women report emotions such as self-consciousness, embarrassment,[12] self-blame, unnaturalness,[13] shame, and reluctance to seek care.[14] They are in a process of adapting to successive impairments.[13] The processes of changed expectations and adjustment to chronic conditions have been discussed in relation to other health conditions[15–18] and are relevant to women with pelvic floor dysfunction. In a qualitative analysis of 14 women awaiting surgery for POP, themes expressed included women's role limitations, poor sexual function, restricted physical activity, and decreased self-esteem.[19] The difference between our findings and the themes from the study of women awaiting surgery for POP is the sustained, emotional, and life-changing trajectory of women who experience repair of mesh complications. The severe pain, despair, and permanent loss of physical and socioemotional health among women with mesh complications are notably amplified.

In addition, the women in our study had expectations before mesh placement that were completely reversed after the surgery. Taken in this context, the perceived failure of mesh placement constitutes an identity stressor,[20] precipitating a perception of spoiled identity[21,22] for some women. The necessity to redefine one's identity has been discussed in the context of disability, in which participation in collective strategies such as activism has been correlated with self-esteem.[23] The aftermath of perceived failed treatment has been discussed in the context of epilepsy surgery by Derry and Wiebe,[24] who pointed out that "failure is a judgment based on pre-operative expectations" and advised the careful shaping of preoperative understandings, information, and counseling to appraise the outcomes and postsurgical support groups.

After the Food and Drug Administration Public Health Notification[4] and the release of the American Urogynecologic Society Informed Consent Toolkit,[25] physicians now have improved information on which to shape presurgical expectations. Our study suggests that patients would value longer follow-up by their original surgeons to identify and manage complications. The psychological effects of those complications may be less severe the sooner these are addressed.

Many patients with vaginal mesh complications experience degraded emotional health, which is often not addressed by the physicians with whom they have sought treatment. We also rarely address the fact that they have been adjusting, in various ways, to pelvic floor dysfunction for years and are now in the process of adapting to successive impairments. Busy clinic schedules and the short-term nature of tertiary care often prohibit in-depth discussions about body image, personal relationships, changed intimacy, and other changes women experience after sustaining complications from mesh surgery—yet, many women have no one else with whom to share these troubling issues. Patients seeking care in tertiary centers are discharged when their complications have resolved or their physicians feel that they have exhausted all treatment options. Some of our patients surveyed described feeling hopeless when we informed them that "there was nothing else we can do" and also perceived this statement as an unwillingness to help.

We undertook this quality improvement project to better understand how women fare after we have treated them for their mesh complication to the best of our abilities. Two key facts stand out: (1) concomitant with ongoing research to improve the safety of vaginal mesh procedures, there must be dedicated efforts to develop and study a range of therapies for holistically treating women with mesh complications and (2) surgeons, in particular those at tertiary care centers caring for women with mesh complications, should recognize the emotional journey these women are on and take time in the clinical encounter to acknowledge the changes wrought in their lives. On the basis of the fact that most women fell into the 2 negative trajectories, we believe that tertiary care centers should provide a counseling component as part of a multidisciplinary care team. Because many women live remotely from the tertiary care center, this could take the form of a telephone- or web-based intervention.

We welcome creative solutions to address the problem of women feeling abandoned when discharged from the tertiary care center, their clinic of last resort. It is impractical and expensive to see patients frequently after our therapies have been optimized, and indeed, continuing visits to a surgeon creates the impression that surgery is still possible to cure the patient's symptoms. Focus groups with patients experiencing mesh complications could be helpful in identifying strategies to aid women in each of the identified trajectories. We should also encourage collective strategies such as support groups, which are associated with improved self-esteem. More research is needed to determine what types of groups (ie, online, telephone, face-to-face) would provide the kinds of support best suited to women in each recovery trajectory.

The strength of this study lies in the patient perspective provided by our qualitative analysis. Although a quantitative study can show that vaginal mesh complications frequently affect quality of life, this study shows the extent to which those lives have been affected in a manner not feasible by quantitative methods. Other strengths include the large sample size and long-term follow-up (mean of 2.3 years from initial presentation and 4.5 years from initial mesh placement).

There are limitations to our study. Our results are not representative of all women with mesh complications, only those seeking treatment in tertiary care centers. However, as cited in our companion article, only 45% of the women seen in our clinic had previously been treated for mesh complications, and only 18% of the women who provided qualitative data had undergone further treatment of mesh complications since they were last seen at our clinic.[10] Most women were being seen in our clinic for the first time. In addition, open-ended responses were shorter than those typically used in qualitative analysis.

Many women continue to experience vaginal mesh complications, even after their physicians believe that they have been successfully treated. More than half of the women who responded consider their outcomes unsatisfactory after optimized treatment in a tertiary care center. This study suggests that we need to develop and study a new and increasingly humanistic framework for treating vaginal mesh complications.

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Int Urogynecol J (2014) 25:465–470
DOI 10.1007/s00192-013-2227-3

ORIGINAL ARTICLE

Short-term surgical outcomes and characteristics of patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery

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Received: 5 June 2013 / Accepted: 1 September 2013 / Published online: 2 October 2013

Abstract
Introduction and hypothesis Surgical treatment of pelvic organ prolapse (POP) and stress urinary incontinence (SUI) can include the use of synthetic materials. Placement of synthetic materials into the vaginal wall, through either the vagina or the abdomen, includes the risk of complications such as vaginal wall extrusion or pain. There is little data regarding outcomes following treatment of mesh complications.
Methods A retrospective chart review of patients who underwent excision of mesh placed for POP or SUI between 1 January 2001 and 31 October 2012 was performed at the University of Virginia. Chart abstraction queried patient demographics, clinical history, physical examination, pre- and post-excision symptoms, and operative findings. The International Continence Society (ICS) and International Urogynecological Association (IUGA) classification system was used to define the nature and location of mesh complications.
Results A total of 57 patients (26 mid-urethral slings, 23 transvaginal prolapse, 9 intraperitoneal prolapse) with the diagnosis of mesh extrusion into the vaginal wall were analyzed. Twenty-five (average 2.8 cases/year) original mesh surgeries occurred between January 2001 and January 2010 and 41 (average 20.5 cases/year) occurred after January 2010. The most common presenting patient complaints were chronic pelvic pain (55.9 %), dyspareunia (54.4 %), and vaginal discharge (30.9 %). At a 6-week post-operative visit, 57.3 % of patient's symptoms were completely resolved and 14.6 % were improved.
Conclusion Clinicians should be cognizant of the variable presentations of post-operative vaginal mesh complications. Mesh excision by experienced pelvic surgeons is an effective and safe treatment for these complications; however, a significant number of patients may have persistent symptoms following surgery.

Keywords Pelvic organ prolapse · Stress urinary incontinence · Vaginal mesh · Post-operative complications · Pelvic pain

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Introduction

Pelvic organ prolapse (POP) and urinary incontinence are prevalent disorders in women older than 50 years with the rates of incontinence increasing linearly with age [1, 2]. The treatment of POP and stress urinary incontinence can include the use of synthetic materials, including prosthetic mesh. The outcomes and complications of prosthetic mesh placement to treat stress urinary incontinence have been evaluated with multiple randomized trials and long-term follow-up. Nine-year erosion rates from vaginal tape used to treat stress urinary incontinence have been reported to be 2.5 % [3]. Unfortunately, there is a paucity of data regarding long-term outcomes and complication rates for the use of transvaginally placed mesh for treatment of pelvic organ prolapse, and even less for outcomes following the management of vaginal mesh complications. Transvaginal mesh procedures can be associated with potential adverse post-operative side effects such as pain, exposure, bleeding, and recurrent pelvic floor symptoms. These reported complications increased such that the Food and Drug Administration (FDA) issued warnings in 2008 and 2011 regarding the use of synthetic mesh in transvaginal POP because of concerns regarding unnecessary risk exposure [4, 5].

After noting a sharp increase in the number of outpatient referrals to our clinic with vaginal mesh complications, we performed a retrospective chart review in order to examine

patients' presenting symptoms, post-operative symptoms, and operative findings. We sought to elucidate patient outcomes, in order to improve pre-operative counseling-related mesh complication treatment and symptom resolution.

Materials and methods

Institutional review board approval was obtained for this retrospective chart review. Subjects were identified by analyzing the case logs of the female pelvic medicine and reconstructive surgeons at the University of Virginia. Eligible electronic medical records for review included those of any patient who underwent transvaginal or abdominal mesh excisions between 1 January 2001 and 31 October 2012. Other inclusion criteria included: patients 18 years of age or older, presentation to the female pelvic medicine and reconstructive surgery clinic with a pre-existing diagnosis of mesh exposure or extrusion through the vaginal wall, vaginal mesh contracture, or patients who were diagnosed during the clinic visit, and subsequently underwent surgical excision. Chart review included patient demographics, clinical history, physical examination, pre- and post-excision symptoms, and operative findings. The International Urogynecological Association (IUGA) and International Continence Society (ICS) created a classification system for complications directly related to the insertion of prostheses into female pelvic floor surgery in 2011 [6]. The IUGA/ICS classification system was employed to define the character, timing, and location of the complications. Descriptive statistics and standard *t* tests were performed using Excel Office 2007.

Results

A total of 57 patients with the diagnosis of vaginal mesh complications were analyzed with a total of 66 procedures performed. Two patients required three procedures and five patients required two procedures for complete excision of the extruded or symptomatic mesh. Patient and mesh excision surgery characteristics are listed in Tables 1 and 2. The patients were primarily classified by the type of original mesh placed, although more than one type of mesh may have been implanted. Twenty-six patients had a mid-urethral sling placed to treat SUI, 23 patients had transvaginal mesh placed to treat POP (vaginal prolapse mesh), and 9 patients had an abdominal sacrocolpopexy (intraperitoneal prolapse mesh) to treat POP. The majority of patients were white (92.6 %), the average parity was 2.8, and the average BMI was 28.0. Fifteen patients (21.4 %) admitted to smoking tobacco prior to or at the time of presentation, and 30 (42.9 %) had been treated with vaginal estrogen, hormone replacement therapy, or were premenopausal prior to referral.

There were 66 total mesh excision surgeries; 25 (average 2.8 cases/year) original mesh surgeries occurred between January 2001 and January 2010 and 41 (average 20.5 cases/year) occurred after January 2010. Prior to 2010, the majority of mesh excisions were mid-urethral slings (45.8 %), followed by intraperitoneal mesh (37.5 %) and vaginal prolapse mesh (16.7 %). However, after 2010, the percentage of vaginal prolapse mesh excisions increased to 50 %, while both mid-urethral slings and intraperitoneal mesh excision decreased (37 % and 17 % respectively).

The majority of procedures to excise extruded or symptomatic mesh were outpatient procedures (84 %) and were performed vaginally (91.4 %). Only 6 cases (8.5 %) of mesh complications originated from an abdominal sacrocolpopexy (ASC) requiring an abdominal incision. Patients undergoing an intraperitoneal mesh excision as compared to other mesh excisions trended towards increased intra-operative estimated blood loss but did not require transfusion, and this finding did not reach statistical significance ($p=0.053$). Only one intra-operative complication, an episode of supraventricular tachycardia, was reported (1.5 %). Two serious post-operative complications included a pulmonary embolus and sepsis in separate patients from the intraperitoneal mesh excision group (3.0 %).

Presenting symptoms of patients evaluated with vaginal mesh-related complications are seen in Fig 1. The most common presenting complaints for all mesh-related complications

Table 1 Patient characteristics

Mesh type		Vaginal prolapse	Mid-urethral	Intra-peritoneal	Total
Age		58.7±12.1	53.3±13.5	62.3±12.1	57.3±13.0
BMI		27.9±5.6	29.0±5.8	26.4±5.9	28.0±5.7
Parity		2.6±1.5	2.6±1.4	3.3±1.7	2.8±1.5
Vaginal estrogen, HRT, premenopausal		37.0 %	53.60 %	33.3 %	42.90 %
Tobacco		25.9 %	10.7 %	33.3 %	21.40 %
Race	Caucasian	92.6 %	96.4 %	93.3 %	94.3 %
	African–American	3.7 %	0.0 %	0.0 %	1.4 %
	Other	3.7 %	3.6 %	6.7 %	4.3 %

Table 2 Mesh excision surgery characteristics

Mesh type		Vaginal prolapse	Mid-urethral	Intra-peritoneal	Total
Number of patients with one mesh type complication		20	22	11	53
Number of patients with more than one mesh type complication		4		0	4
Total number of mesh type complications		24	26	11	61
Reoperation for additional mesh type complications	One mesh type	2	1	4	9
	More than one mesh type	1		0	
Total number of mesh excisions		27	28	15	70
Vaginal (vs abdominal) operative approach		100 % (27/27)	100 % (28/28)	60 % (9/15)	91.4 % (64/70)
Operative time (min)		79.0±38.7	53.5±33.8	93.2±76.0	71.3±47.3
Estimated blood loss (mL)		43.0±41.3	33.9±38.6	131±142.4	58.2±82.6
Intra-operative complications		0	0	1 (SVT)	1
Post-operative complications		Vaginal bleeding (1), candidiasis (1), UTI (1)	UTI (3), prolonged catheterization (2), candidiasis (1)	Wound infection (5), superficial hematoma (2), sepsis (2), atrial fibrillation (1), PE (1), BV (1)	21
Length of hospital		92.6 % outpatient, inpatient POD 1±0	89.2 % outpatient, inpatient POD 1±0	60.0 % outpatient, inpatient POD 3.2±1.5	84.3 % outpatient, inpatient POD 2.2±1.5

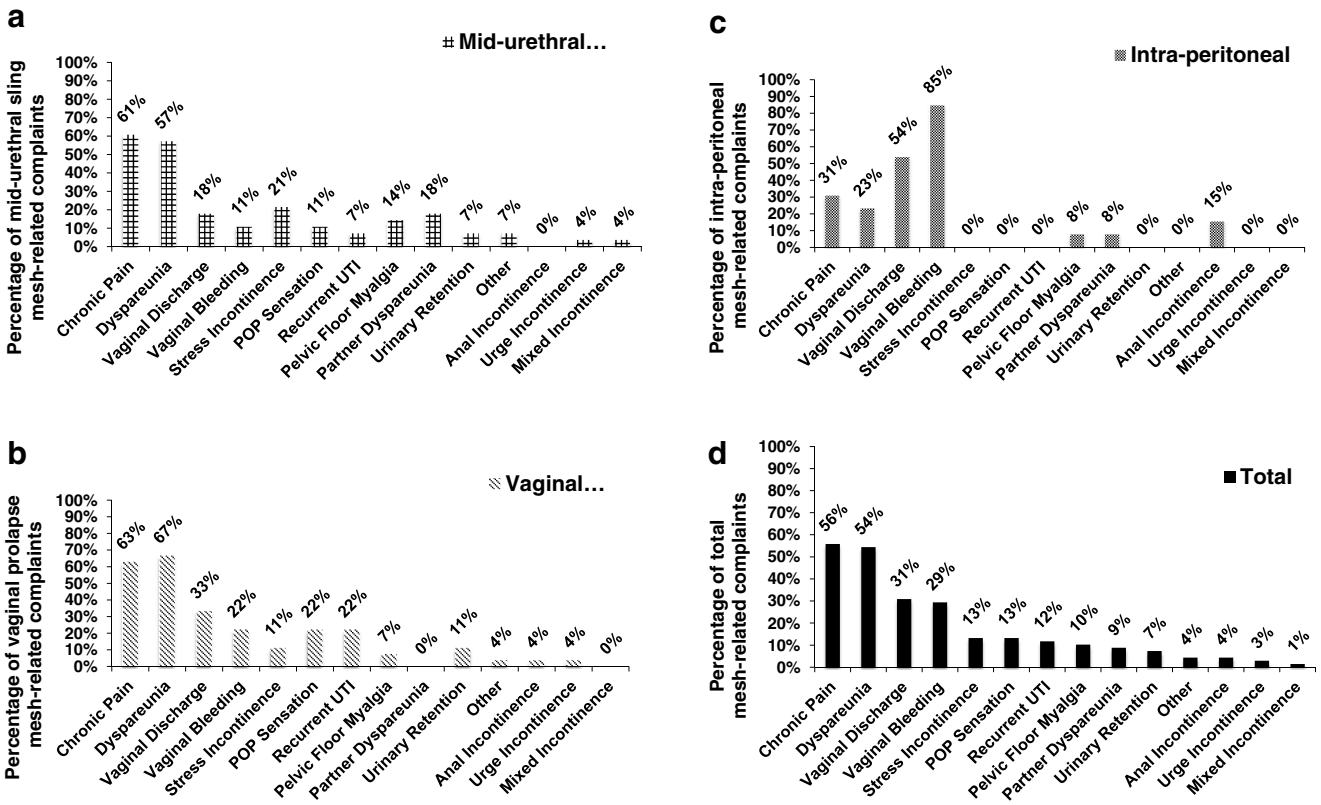

Fig. 1 Presenting symptoms of patients evaluated with vaginal mesh-related complications

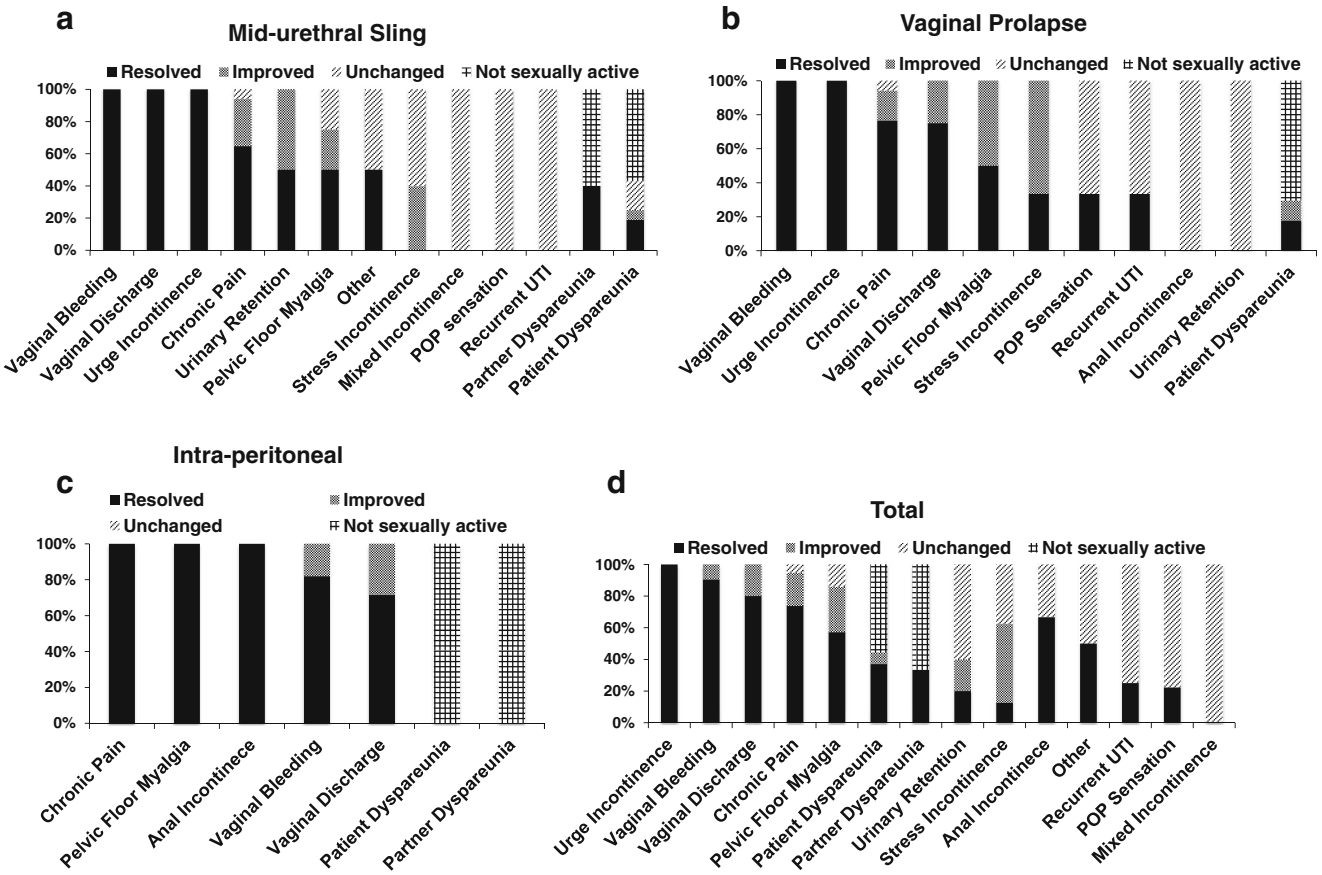

Fig. 2 Breakdown of symptom improvement for all mesh types

were chronic pelvic pain ($n=38$, 55.9 %), dyspareunia ($n=37$, 54.4 %), and vaginal discharge ($n=21$, 30.9 %). Lower urinary tract complaints such as recurrent infections, incontinence, and retention were also common presenting symptoms ($n=25$, 36.8 %). At a 6-week post-operative follow-up visit, over half of patients had either complete symptom resolution or improvement, with 57.3 % of patients' symptoms completely resolved and 14.6 % improved. The breakdown of symptom improvement for all mesh types is seen in Fig. 2. In all mesh types complaints of dyspareunia by the patient and/or partner were either improved or resolved (42.4 %); however, 57.5 % of patients were not sexually active. All patients in our series with vaginal bleeding, vaginal discharge, and urge incontinence symptoms had experienced either resolution or improvement, and 95 % of patients with chronic pain symptoms had resolution or improvement post-operatively. When analyzed by mesh types, symptom improvement was comparable with the exception of stress incontinence and urinary retention (Fig. 2c, d). Urinary retention or incomplete bladder emptying resolved or improved in 100 % of patients after mid-urethral sling excision, but no voiding improvement was seen in patients after vaginal prolapse mesh excision. Stress incontinence improved or resolved in all patients after vaginal prolapse mesh excision, but only improved in 40 % of patients after mid-urethral sling excision.

The IUGA/ICS classification of mesh complications in this cohort are shown in Fig. 3. 87.5 % of patients presented with vaginal complications (category 1–3) and 96.2 % of patients were symptomatic (Fig. 3b–d). While none of the patients analyzed in our series had an immediate mesh complication (T1), 33.7 % reported diagnosis of mesh complication within 2 to 12 months (T3) and 64.4 % after 1 year (T4). The most common site of exposure was the suture line, 55.8 % (S1), while 36.5 % were away from the suture line (S2).

Discussion

According to our retrospective chart review, the number of referrals to the University of Virginia Female Pelvic Medicine and Reconstructive Surgery clinic for mesh complications has increased seven-fold in the last few years; thus, we have performed an increased number of mesh excisions. This increased experience has led to a more detailed understanding of mesh-related complications; specifically, we have been able to compare pre- and post-operative symptoms in three mesh types. Additionally, the adoption of the IUGA/ICS classification

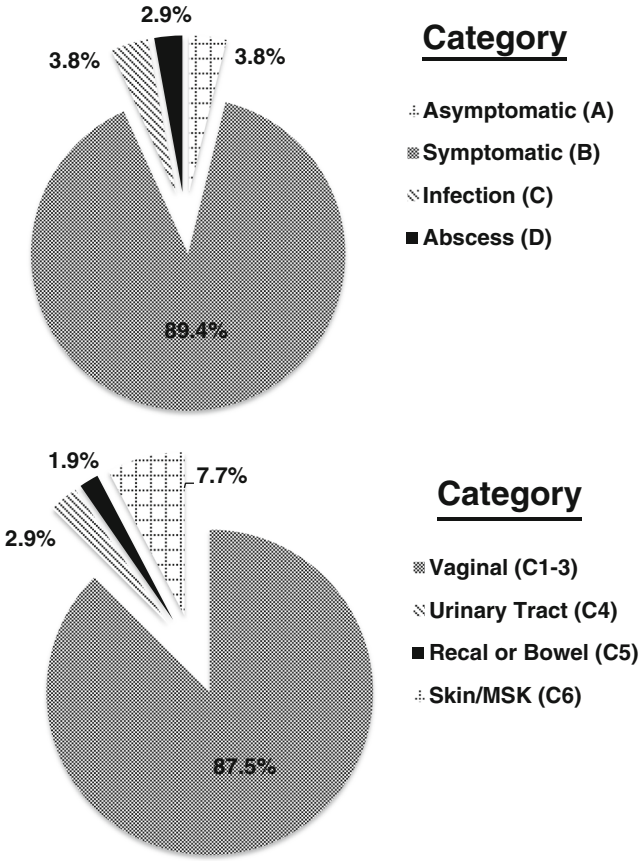

Fig. 3 International Urogynecological Association (IUGA)/International Continence Society (ICS) classification of mesh complications in this cohort

system has enabled us to categorize mesh extrusion characteristics, location, and timing.

The exact rate of vaginal mesh extrusion is not known; however, it is estimated to be between 10 and 20 %. Abed et al. performed a systematic review in Medline reports of adverse events after vaginal prolapse repairs using graft materials and found an overall rate of 10.3 % of mesh extrusion in 110 studies [7]. A multicenter, double-blind randomized control trial was designed by Sokol and colleagues to evaluate the objective and functional outcomes of vaginal mesh for POP, but this study was halted early owing to a high rate of mesh exposures (15.6 %) [8].

In our series, the number of mesh excision surgeries has increased in the last several years and 91 % of mesh excisions were successfully performed vaginally. Successful excision of mesh transvaginally has been demonstrated in other studies [9, 10], but symptom resolution after mesh excision has not been adequately described. Feiner and colleagues performed a systematic review and found objective success rates of mesh excision from 86.8 % to 95.4 %; however, they did not evaluate the post-operative resolution of symptoms [11]. Indications for mesh excision include dyspareunia, chronic pelvic pain, vaginal bleeding/discharge, and infections [12]. While most mesh excisions can alleviate or improve a patient's symptoms, they are not always effective. At a 6-week post-operative follow-up visit 57.3 % of patients' symptoms were completely resolved or improved, and, most impressively, 95 % had complete resolution or improvement in chronic pain post-operatively. There was also a 42.4 % complete resolution or improvement in dyspareunia, but 57.5 % of patients were not sexually active in our series. Similarly in a smaller review of 15 patients, Ridgeway et al. had 86 % improvement in vaginal pain with only 33 % of patients still sexually active [13]. Reviews on symptom resolution have been reported by Marguiles (9 patients with 77 % resolution of vaginal pain) and Feiner and Maher (17 patients with 88 % reduction in vaginal pain), but their studies involve smaller sample sizes and do not expound upon other pre- and post-operative symptoms [14, 15].

In 2011 the IUGA/ICS created a terminology and classification system for complications directly related to the insertion of prostheses in female pelvic floor surgery [6]. Skala et al. performed a retrospective analysis of 179 patients with complications related to vaginal mesh used in prolapse or incontinence surgery and employed the IUGA/ICS classification system to categorize the complications. Presenting symptoms included vaginal/pelvic pain (43 %), vaginal discharge (16.8 %), vaginal bleeding (8.4 %), and urinary urgency (45.3 %), and mesh erosion was diagnosed in 67 patients (37.4 %). Unfortunately, they did not address symptom resolution after mesh excision. Similar to our study, most patients were categorized T3 and T4 [16]. While the IUGA/ICS classification system is a useful tool for categorizing severe adverse events, it is difficult to compare the multiple subgroups given the large number of variables.

The strengths of our study include the detailed data available from the electronic medical record, the high rate of 6-week post-operative visits with no loss to follow-up, the good distribution of mid-urethral sling and prolapse mesh extrusions, and the experience of two fellowship trained attendings. Limitations of our findings include its retrospective nature, the small number of cases, the heterogeneity of synthetic materials and types, and limited follow-up period. We were also unable to calculate rates of mesh erosion owing to an unknown denominator of total mesh cases. Furthermore, our position as a tertiary care center may overestimate the number of women requiring surgical excision, while some cases of mesh exposure can be treated with tropical estrogen or in office procedures. Nonetheless, we believe our findings may assist clinicians in the counseling of patients relative to treatment options for mesh complications.

Conclusions

Clinicians should be cognizant of the variable presentations of post-operative vaginal mesh complications. Transvaginal

mesh excision by experienced pelvic surgeons is an effective and safe treatment of these complications with good symptom improvement or resolution; however, a significant number of patients may have persistent symptoms (particularly pelvic pain and lower urinary tract complaints), following surgery.

Financial disclaimers/conflict of Interest None.

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Long-Term Follow-up of Treatment for Synthetic Mesh Complications

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Objectives: The objectives of this study are (1) to describe the presenting symptoms, findings, and treatment and (2) to describe the self-reported improvement and function at least 6 months after presentation in women presenting to 1 urogynecology division for complications associated with synthetic vaginal mesh.

Methods: Women evaluated between 2006 and 2011 were identified by diagnostic codes. We abstracted information from the medical record and attempted to contact all women to complete a follow-up telephone survey questionnaire consisting of several validated instruments.

Results: A total of 111 women were evaluated for complications associated with synthetic vaginal mesh. The mean interval from index surgery was 2.4 years. Of these, 84% were referred from outside hospitals. Index surgeries included vaginal mesh kits/vaginally placed mesh (47%), midurethral mesh slings (37%), abdominally placed vaginal mesh (11%), and vaginal mesh kit with concomitantly placed mesh sling (5%). The most common complications were extrusion (65%), contraction (17%), and chronic pelvic pain (16%). A total of 98 women underwent some type of treatment (85 surgical) by urogynecologists, pelvic pain specialists, or physical therapists. Eighty-four (76%) provided follow-up information at mean interval since presentation of 2.3 years. At follow-up, the mean (SD) Pelvic Floor Distress Inventory score was 98 (67), the mean (SD) EQ-5D index score was 0.69 (0.23), and 22% reported vaginal discharge, 15% vaginal bleeding or spotting, and 45% sexual abstinence due to problems related to mesh. A total of 71% reported being overall better, whereas 29% were the same or worse.

Conclusions: Two years after tertiary care level multidisciplinary treatment of vaginal mesh complications, many women still report symptoms that negatively impact their quality of life.

Key Words: pelvic organ prolapse, stress urinary incontinence, mesh complication, vaginal mesh

(*Female Pelvic Med Reconstr Surg* 2014;20: 126–130)

Pelvic organ prolapse (POP) and stress urinary incontinence (SUI) are common disorders in women, occurring in up to 50% and 30% of women respectively and having great impact on the quality of life.[1,2] With the primary treatment being surgery, transvaginal mesh products were introduced over the last decade with the intent of improving success rates of traditional POP and SUI repair methods, whose recurrence rates are reported as up to 30%.[2,3] Along with the increased use of vaginal mesh, there has been an increased incidence of complications unique to this repair method. A 2008 Food and Drug Administration Public Health Notification and the 2011 update described no symptomatic benefit of transvaginal mesh use but additional risks including, although not limited to, vaginal mesh exposure and contraction.[4,5] The Systematic Review Group of the Society of Gynecologic Surgeons revealed an overall mesh exposure rate of 10.3%, with a range of 0% to 29.7%.[6] The implications of mesh complications can be demonstrated by the example of 1 study where a 5-year cumulative risk of repeat surgery was found to be significantly higher for vaginal mesh repair over traditional POP repair, specifically for mesh removal/revision.[7]

To date, there are scant data about whether treatments for women with mesh complications are successful in alleviating their symptoms, especially long term. In a recent abstract, 50% of women reported persistent pain and 25% dyspareunia after treatment of mesh complications (Crosby EC, Berger MB, DeLancey JL, Fenner DE, Morgan DM. Symptom resolution after operative management of complications from vaginal mesh. Presented at the American Urogynecologic Society Annual Scientific Meeting on October 3, 2012).

Similar to other recent reports, our institution has seen an increase in volume of women referred for mesh complications over the past decade.[8] We thus undertook this project to better understand the experiences and outcomes of women referred to and treated in our clinic, with the hopes of improving our own processes related to their care. Because any synthetic mesh can cause complications after surgical implantation, we included mesh placed abdominally for POP and mesh slings placed for SUI.

The objectives of this study are (1) to describe a cohort of women presenting to our division over 6 years for complications associated with synthetic vaginal mesh and (2) to describe self-reported improvement and function at least 6 months (mean, 2.3 years) after treatment in our center.

METHODS AND MATERIALS

This study involved both retrospective chart review and follow-up survey questionnaire for women presenting for vaginal mesh complications to the Division of Urogynecology and Pelvic Reconstructive Surgery at the University of Utah between January 1, 2006 and December 31, 2011. The study protocol and instruments were reviewed by the University of Utah institutional review board, which deemed it exempt from review. We identified 221 women with 1 of the following *International Classification of Diseases, Ninth Revision* diagnostic codes: mesh erosion 939.2, mechanical complication of graft 996.39, pain due to genitourinary device/implant 996.76, infection of genitourinary device/implant/graft 996.65, unknown foreign body 939.0, mesh excision vaginal 57295, mesh excision abdominal 57296. Each medical record was reviewed, and participants were excluded

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Reprints are not available.
The authors have declared they have no conflicts of interest
This investigation was supported by the University of Utah Study Design and Biostatistics Center, with funding in part from the National Center for Research Resources, the National Center for Advancing Translational Sciences, and the National Institutes of Health, through grant 8UL1TR000105 (formerly UL1RR025764).

DOI: 10.1097/SPV.0000000000000084

whose initial surgery was something other than a vaginal mesh kit for prolapse, abdominal sacrocolpopexy with mesh for prolapse, or suburethral sling for urinary incontinence. In addition, we excluded women presenting for surgical complications due to foreign bodies other than synthetic mesh (ie, biologic allograft, xenograft, or suture), complication presentation outside the study period, or whose only complaint was surgical failure (ie, recurrent prolapse or incontinence). Electronic and paper charts of eligible women were abstracted for demographics, medical history, details of original mesh surgery, symptoms at presentation, mesh complication diagnoses, treatment modalities, and number of visits. We defined operating time as the length of the procedure in minutes.

After the chart review, we performed a follow-up survey questionnaire. We mailed each patient a letter describing our follow-up project and allowing each to opt out. The letter stated our intent to contact the patient by telephone to ask questions about her progress since her last visit with us. Women were also given an option to respond by written questionnaire. The conducted survey included 44 questions, 3 regarding follow-up treatment since last visit; 20 questions from the Pelvic Floor Distress Inventory (PFDI-20) short form; 4 additional questions addressing vaginal discharge, spotting, and sexual activity; 7 questions modified from the Pelvic Floor Impact Questionnaire (PFIQ) short form by changing the stem to, "In the past 3 months, have problems related to your mesh surgery affected your:…" and by reporting answers on a scale of 0 to 100 (0 correlating with "not at all" affected and 100 representing "greatly" affected).[9] Thus, higher PFIQ scores correspond to greater dysfunction. We also included 5 health status questions from EQ-5D; these refer to "your health today" using 5 domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), with 3 response options (no problems, moderate problems, severe problems).[10] In addition, we used a modified EQ-VAS (verbally reported scale instead of visual analog) prompting for overall health state on a scale of 0 to 100, where 0 represents the "worst possible health state" and 100 represents the "best possible health state." We included 2 multiple-choice questions regarding overall improvement since the treatment at our institution and satisfaction with the clinic experience. In addition, women responded to several open-ended questions about their experience; these are addressed in the companion paper.[11]

This is a descriptive study; results are presented in aggregate form and by mesh type, and the sample size is insufficient to allow comparisons between groups. The PFDI answers were scored in the usual fashion to give a total score with possible results ranging from 0 to 300, the higher number representing greater dysfunction. The PFIQ short form answers were resulted as medians with interquartile ranges. EQ-5D results were calculated in 2 forms, first as a simple aggregate of "any reported problem" and second as a scored index. To calculate the overall EQ-5D index, we applied the scoring algorithm for the US general population as described by Shaw et al via the Microsoft Excel calculator provided by the Agency for Healthcare Research and Quality.[12,13]

RESULTS

One hundred eleven women met the inclusion criteria and are the subject of our study. Of these, 16 women (14%) had complications from within our hospital system (none of which included vaginally placed mesh for POP), and 93 (83.7%) were referred from outside hospitals, with 2 unknown/unstated referral sources. In women presented after procedures performed at nearly 20 different surgical facilities, 79 (71%) occurring within the state of Utah, 31 (28%) from 8 outside states, and 1 unknown. Eighty women (72%) were referred by a source other than the original surgeon (ie, women were referred by friends, other physicians or clinicians, or self-referred). Table 1 summarizes the study population characteristics. The mean interval from the placement of mesh to the presentation at our institution was 2.4 years (range, 7 days to 16.3 years). We were able to obtain and review operative reports of the index mesh

TABLE 1. Participant Characteristics

Age, mean (SD), y	54.6 (13.1)
BMI, mean (SD), kg/m^2	28.1 (5.5)
Parity, mean (SD)	3.2 (2.0)
Race, n (%)	
White	79 (67)
Hispanic	4 (3.6)
Asian	1 (0.9)
Unknown/not recorded	32 (28.8)
Marital Status, n (%)	
Married	86 (77.5)
Divorced	14 (12.6)
Widowed	6 (5.4)
Single	4 (3.6)
Unknown/not recorded	1 (0.9)
Insurance, n (%)	
Private	69 (62.2)
Public	36 (32.4)
None	4 (3.6)
Unknown	2 (1.8)
Tobacco use, n (%)	
Current use	19 (17.1)
None	92 (82.9)
Medical comorbidities, n (%)	
Depression/anxiety	32 (28.8)
Fibromyalgia/chronic pain	21 (18.9)
Diabetes	12 (10.8)
None	47 (42.3)
Medication use, n (%)	
Pain medication	45 (40.5)
Antidepressant	36 (32.4)
Hormone	33 (29.7)
Anxiolytic	22 (19.8)
Neuromodulator	16 (14.4)
Insulin/oral antiglycemic	12 (10.8)
Steroid	1 (0.9)
None	33 (29.7)
Prior pelvic surgery, n (%)*	
Hysterectomy	57 (51.4)
Cesarean	16 (14.4)
POP	25 (22.5)
No mesh	20
With mesh	5
SUI	10 (9)
No mesh	7
With mesh	3

*Before index surgery leading to complication.

Pain medication indicates NSAID or narcotic; BMI, body mass index.

surgery for 104 women (94%). Fifty women (45%) had undergone intervention before presentation at our institution, 34 (68%) of which included excision of mesh. Of the 111 women seen for mesh complications, 52 were following vaginal mesh kits or vaginally placed mesh, 42 had complications from midurethral mesh slings (of these, 7 were from mini-slings), 12 from abdominally placed vaginal mesh, and 5 from both a vaginal mesh kit and from a concomitantly placed mesh sling. Among complications, there were 7 different marketed mesh kit products represented (9 anterior only, 6 posterior only, 2 anterior and posterior, and 33 total or apical), 12 different midurethral sling products, and 3 different synthetic mesh grafts for abdominally placed vaginal mesh. Thirty-two patients had additional mesh products placed at the time of the index surgery that on evaluation were not contributing to patient symptoms—26 of 52 women (50%) with complications from vaginally placed mesh had also undergone simultaneous placement of a mesh sling, which was found to be uncomplicated; 4 of 42 women (9.5%) with complications from mesh slings also had uncomplicated vaginally placed mesh in place; and 2 of 12 women (16.7%) with abdominally placed mesh had uncomplicated mesh slings in place.

The most common symptoms at presentation to our clinic were pain (77/111, 69%), dyspareunia (55/111, 49.5%), vaginal discharge (31/111, 27.9%), and vaginal bleeding (23/111, 20.7%).

After evaluation, we identified 72 women (64.9%) with vaginal mesh extrusion, 19 (17.1%) with mesh contraction, 18 (16.2%) with chronic pelvic pain, 10 (9%) with obstructive voiding, and 4 women (3.6%) with mesh erosions into bladder/bowel (please note that diagnoses are not exclusive).

The most common site of mesh extrusion was the anterior vaginal wall (n = 32) followed by the vaginal apex (n = 23), midurethra (n = 15), and posterior vagina (n = 12), with 10 of these representing multiple sites of mesh extrusion in the same patient (8 women with 2 sites of mesh extrusion and 1 patient with 3 sites of extrusion).

After evaluating these 111 women, 13 received no intervention by our physicians due to recommendations for watchful waiting (2), referral to other specialist (2), lost to follow-up (1), or second opinion only/referred back to index surgeon/lack of insurance compatibility (8). Among the 98 women receiving intervention, the mean number of visits to our institution was 5.8 (range, 2–30). Eighty-five women (86.7%) underwent mesh excision, 82 ultimately in the operating room and 3 exclusively in the clinic. The mean (SD) number of excisions was 1.2 (0.5), and the mean (SD) operative length for the first excision was 86.0 (49) minutes (range, 12–259 minutes). An additional 13 women underwent second mesh excision with mean (SD) operative length of 94.9 (75) minutes (range, 12–248 minutes), and 3 of those women underwent third excision with mean (SD) operative length of 88.8 (24) minutes (range, 103–146 minutes). Perioperative complications were rare and included 2 intraoperative consultations, 1 with general surgery for resection of appendix adherent to mesh in a patient with erosion after an abdominal sacrocolpopexy and a consultation with colorectal surgery for colonoscopy to evaluate for mesh erosion. In addition to surgical treatment, 31 women (31.6%) received vaginal estrogen, 10 women (10%) received trigger point injections, and 9 (9.2%) received oral neuromodulators. Ten women (10%) were evaluated and treated by our pelvic pain specialist, and 12 (12.2%) were referred for physical therapy.

After medical record review, we attempted to contact the 111 women for our follow-up questionnaire. Contact information was incorrect or outdated for 10, 1 woman was excluded because of language barrier, 1 woman was deceased, and 11 women did not respond to contact attempts. Thus, we were able to contact 88 women. Of these, 5 requested the mail-in paper survey (and 2 returned it), and 1 of these subsequently declined participation. Thus 84 of 111 (76.1%) ultimately provided follow-up data; 1 woman opted to only answer 1 of the open-ended qualitative questions, and 1 woman omitted the PFIQ and EQ-5D.

The mean time from initial presentation to our clinic to follow-up survey was 2.3 years (range, 209 days to 6.5 years). Since their last visit with our clinic, 15 women had received additional treatment elsewhere for mesh-related problems (physical therapy, n = 6; surgical excision, n = 5; medical therapy, n = 3; other, n = 3), 8 were treated for POP (physical therapy, n = 4; surgical treatment, n = 4), and 5 for SUI (physical therapy, n = 1; surgical treatment, n = 2; medical therapy, n = 3).

The mean (SD) overall PFDI score at follow-up was 98 (67) of 300. The mean (SD) PFDI scores were 112.5 (74) for women seen for complications of transvaginally placed mesh alone, 96.8 (61) for mesh sling alone, 59.1 (31) for transabdominally placed mesh, and 58.4 (70) for transvaginal mesh with mesh sling. Forty-four women (54%) reported pain or discomfort in the lower abdominal/genital region (affirmative response to PFDI question, "Do you usually experience pain or discomfort in the lower abdomen or genital region?"). The PFDI subscale scores are summarized in Table 2.

Vaginal discharge was reported by 22% (n = 18) of women, most frequently described as "somewhat bothersome" on a 4-point scale (not at all bothersome, somewhat bothersome, moderately, or quite a bit bothersome). Vaginal bleeding or spotting was reported in 14.6% (n = 12) at follow-up, most frequently reported as "quite a bit bothersome" on the same 4-point scale.

Forty women (48%) at follow-up reported being currently sexually active; of these, 21 reported the need to abstain from intercourse from some period because of mesh-related problems since initial surgery. Of those not sexually active (n = 42), 19 (45%) reported abstinence due to problems related to mesh. Of

TABLE 2. Pelvic Floor Distress Inventory Scores at Follow-up

		Complication Attributed to:			
	Entire Population	**Transvaginal Mesh**	**Sling**	**Transabdominal Mesh**	**Transvaginal Mesh + Sling**
PFDI total*	98 (67)	112.5 (74)	96.8 (61)	59.1 (31)	58.4 (70)
POPDI	29.4 (29)	35.6 (34)	28.4 (25)	9.6 (7)	20.8 (22)
CRADI	27.5 (24)	31.2 (25)	25.8 (24)	23.2 (19)	12.5 (21)
UDI	36.6 (28)	37.5 (30)	43.1 (27)	26.3 (23)	10 (8)

*Scores reflect mean (SD).

POPDI indicates POP Distress Inventory; CRADI, Colorectal-Anal Distress Inventory; UDI, Urinary Distress Inventory.

TABLE 3. Modified Pelvic Floor Impact Questionnaire Short Form Results at Follow-up

	Complication Attributed to:				
In the Past 3 Months, Have Problems Related to Your Mesh Surgery Affected Your:	**Entire Population**	**Transvaginal Mesh**	**Sling**	**Transabdominal Mesh**	**Transvaginal Mesh + Sling**
1. Ability to do household chores	20 (0–50)	22.5 (0–52.5)	10 (0–55)	10 (0–23.8)	26 (1.5–56.3)
2. Physical recreation	35 (0–75)	32.5 (0–70)	40 (0–77.5)	17.5 (0–66.3)	38.5 (1.5–75)
3. Entertainment activities	1 (0–55)	0.5 (0–67.8)	20 (0–55)	0 (0–0)	37.5 (19.3–62.5)
4. Ability to travel by car or bus more than 30 minutes from home	6 (0–60)	12.5 (0–70)	15.5 (0–50)	0 (0–0)	26 (1.5–57.5)
5. Participating in social activities outside your home	10 (0–60)	15 (0–70)	10 (0–65)	0 (0–0.75)	32.5 (19.3–55)
6. Emotional health	50 (0–80)	45 (0–80)	50 (0–87.5)	1.5 (0–43.8)	40 (27.5–50)
7. Feeling frustrated	60 (0–81)	60 (21.3–82)	80 (0–95)	4 (0–43.8)	45 (35–50)

*Results are reported as median (Quartile 1–Quartile 3).

currently sexually active women, 31 (77.5%) reported sexual activity that is at least somewhat enjoyable, 24 (60%) reported some amount of pain, and 5 (12.5%) reported that their partner noted pain during intercourse.

Results of the modified PFIQ short form at follow-up are shown in Table 3. Notably, the highest scores reflecting continued problems felt to be related to mesh were reported in the following areas: "feeling frustrated" (median score, 60) and "emotional health" (median score, 50). Results of patient-reported overall health status as assessed by the EQ-5D are shown in Figure 1. The mean (SD) EQ-5D index score was 0.69 (0.23). The mean (SD) EQ-VAS at follow-up (scale, 0–100) was 62.7 (24.5).

Of the 82 respondents, 71% reported being overall better at follow-up than before being seen and treated in our clinic (26.8% were "better," 18.3% "much better," and 25.6% "very much better"), whereas 29% reported being the same or worse than they were before being seen in our clinic (13.4% the "same," 9.8% "worse," 3.7% "much worse," and 2.4% "very much worse") (Fig. 2). Similar trends were seen for the 15 women whose index surgery consisted of solely a suburethral sling, with no concomitant procedures. Of the 10 that underwent sling lysis, 6 were available for follow-up; of these, 1 reported being very much worse, 1 much worse, 1 much better, and 3 very much better. Three of the 5 that underwent mesh excision for extrusion were available for follow-up; of these, 1 reported being about the same, 1 better, and 1 much better.

Finally, of the women surveyed, 88% were satisfied with their overall clinic experience at our institution (35% "extremely satisfied," 38% "very satisfied," 15% "satisfied," 9% "somewhat satisfied," 2% "dissatisfied," 1% "very dissatisfied," and 0% "extremely dissatisfied").

DISCUSSION

Similar to other reports, the most common mesh complications reported in our study were vaginal mesh extrusion and mesh contraction, with subsequent presenting symptoms of pelvic pain, vaginal discharge, and vaginal bleeding.[6,14]

Vaginal mesh placement for POP and SUI continues to put women at risk for complications that can be life altering. In our experience, the treatment of mesh complications requires a significant investment in the form of clinic visits, surgical time, use of additional resources, and intervention before referral (45%). However, after our best efforts at treatment, many women continue to report problems related to mesh placement. We found that mesh complications are difficult to treat successfully, with the majority requiring surgical intervention and multiple visits and nearly 20% of those requiring additional excision. This information can be useful in counseling women regarding the risks and expectations of the treatment of mesh complications.

Two years after treatment (4.5 years after the index mesh surgery), women continue to report symptoms that negatively impact their quality of life. It is also important to note the impact of mesh complications on emotional health. At follow-up, the highest PFIQ scores overall (higher scores corresponding to greater dysfunction) were reported in regards to mesh complications that contributed to emotional health and caused feelings of frustration. Furthermore, the mean EQ-5D index score of

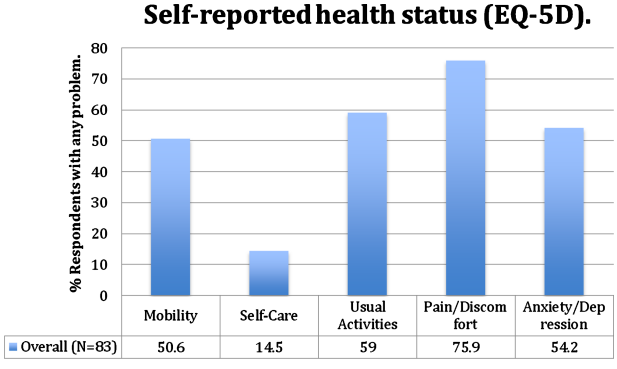

FIGURE 1. Self-reported health status (EQ-5D).

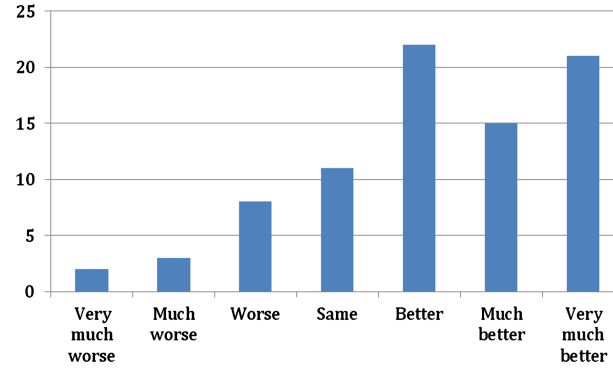

FIGURE 2. Self-reported improvement at follow-up.

0.69 in our study population was generally lower than the US general population norm for women of similar ages, where average indices ranged from 0.84 to 0.89 in US women ages 35 to 64.[15] Similarly, compared with the self-reported health status means of a general population of middle-aged women, EQ-VAS scores from our study at follow-up were also lower, averaging 62.7 compared with reported normal ranges of 80.26 to 86.35.[16]

The number of women referred for complications increased each year of the study period, with 49 women (44%) referred to our clinic during 2011, the final year of our data collection period. Given that the average time between mesh placement and presentation to our clinic was 29 months, this seems to correlate with a continued or increased use of vaginal mesh despite Food and Drug Administration warnings made in October 2008 and July 2011.[4,5] This trend is continuing beyond our study period, as our group saw 136 women with mesh complications in 2012. Similar to other reports, fewer than 25% of women were referred by the surgeon that placed their mesh.[17,18] This may contribute to the continued use of these products, as the physicians placing them may not be fully aware of their own mesh complications.

Although the literature is replete with studies describing the incidence of mesh complications, or how such complications were treated, our study provides new information about how women fare long term after being treated for complications related to mesh placement.[8,14,18–21] Other strengths of our study include the high response rate (84% of women for whom we had correct contact information) and the use of validated instruments to assess various domains of patient-reported outcomes. However, we did not validate the PFIQ after changing the stem to reflect problems related to mesh surgery from the original stem assessing how pelvic floor symptoms impacted various activities.

Although our case series is 1 of the larger ones addressing treatment of mesh complications published to date, we do not have sufficient power to compare outcomes by surgical types. We also excluded complications from nonsynthetic vaginal mesh products, but we recognize unique complications from other types of grafts as well.

In conclusion, our findings demonstrate the impact of vaginal mesh complications on long-term quality of life measures and symptoms. Although women reported high rates of satisfaction with our clinic, this study suggests that there is much room for improvement. We suspect that many more women in our care would benefit from evaluations by other specialists (such as physical therapists, pelvic pain specialists, and mental health specialists), but we were constrained by the long distances many women travel to our clinic, the unavailability of such specialists on the same day as the appointment with us or in their home location, and by insurance plans that covered only specific urogynecologic care. The results of this study, in combination with those gleaned from our qualitative companion manuscript, highlight the need for new multidisciplinary, yet efficient, approaches to managing women with mesh complications. In particular, when feasible, periodic follow-up visits over many years may shed light on previously unreported or new symptoms such that treatment may be offered.

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Outcome of Transvaginal Mesh and Tape Removed for Pain Only

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Abbreviations and Acronyms

MTR = mesh or tape removal

MUS = mid urethral sling

VAS = visual analog scale

Accepted for publication April 7, 2014.

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Purpose: Because there is reluctance to operate for pain, we evaluated midterm outcomes of vaginal mesh and synthetic suburethral tape removed for pain as the only indication.

Materials and Methods: After receiving institutional review board approval we reviewed a prospective database of women without a neurogenic condition who underwent surgery for vaginal mesh or suburethral tape removal with a focus on pain as the single reason for removal and a minimum 6-month followup. The primary outcome was pain level assessed by a visual analog scale (range 0 to 10) at baseline and at each subsequent visit with the score at the last visit used for analysis. Parameters evaluated included demographics, mean time to presentation and type of mesh or tape inserted.

Results: From 2005 to 2013, 123 patients underwent surgical removal of mesh (69) and suburethral tape (54) with pain as the only indication. Mean followup was 35 months (range 6 to 59) in the tape group and 22 months (range 6 to 47) in the mesh group. The visual analog scale score decreased from a mean preoperative level of 7.9 to 0.9 postoperatively ($p = 0.0014$) in the mesh group and from 5.3 to 1.5 ($p = 0.00074$) in the tape group. Pain-free status, considered a score of 0, was achieved in 81% of tape and 67% of mesh cases, respectively. No statistically significant difference was found between the groups.

Conclusions: When pain is the only indication for suburethral tape or vaginal mesh removal, a significant decrease in the pain score can be durably expected after removal in most patients at midterm followup.

Key Words: urethra, pelvic pain, suburethral slings, surgical mesh, device removal

Since the mid 1990s, synthetic mesh slings have become the dominant treatment of stress urinary incontinence, replacing traditional, well established techniques such as autologous fascial slings and Burch colposuspension.[1] In addition, synthetic mesh materials have become popular for various transvaginal pelvic floor prolapse reconstructive surgeries in the last decade. Complication types, rates and management strategies were reported for these synthetic meshes and slings.[2] Despite rapid accrual in the contemporary literature on this specialized management several unanswered questions remain on optimal management.[3]

However, a domain for which little is known to date is pelvic pain after vaginal tape/mesh surgery, especially when considered in isolation and not with an associated complication such as vaginal exposure. The option of mesh or sling removal surgery for pelvic pain relief was suggested. To date the literature includes mostly case reports or small series with a

0022-5347/14/1923-0856/0
THE JOURNAL OF UROLOGY®

http://dx.doi.org/10.1016/j.juro.2014.04.006
Vol. 192, 856-860, September 2014
Printed in U.S.A.

limited number of patients, short followup and no objective tool by which to measure pain at baseline and its degree of improvement after removal surgery.[4–7]

Therefore, we specifically studied the pain symptom outcome in women who underwent MTR surgery for persistent pelvic pain as the only indication for operation.

MATERIAL AND METHODS

After receiving institutional review board approval we analyzed a prospectively collected database from 2005 to 2013 of women without a neurogenic condition who underwent surgery to remove vaginal mesh or tape only because of persistent pain after original placement and had a minimum 6-month followup. Study exclusion criteria included MTR surgery for pain associated with any of certain complications, including mesh exposure, mesh erosion, recurrent urinary tract infections and urinary retention/obstruction. The single reason for tape or mesh removal surgery was pain.

The primary outcome was the pelvic pain level assessed by a simple VAS (range 0 to 10) recorded at baseline at arrival to the clinic by a nurse blinded to patient condition and similarly recorded at each subsequent visit. We evaluated demographics, mean time to presentation after initial placement surgery, pain site and type of mesh or tape. Baseline pain scores were compared with VAS scores at the last visit recorded in the electronic medical record. Pain-free status was defined as a VAS pain score of zero.

The surgical technique of tape removal was reported previously.[8,9] During MUS removal urethrocystoscopy is first performed with a 17.5Fr female urethroscope to locate the course of the tape, which often provokes urethral floor flattening or elevation. A short transverse vaginal incision is then made over the course of the tape to permit access to the lateral extensions of the tape, better control bleeding and facilitate the repair of urethral injury if one occurred during MUS excision. The vaginal incision can be extended into an inverted U shape to allow for insertion of a Martius fat pad graft and/or a fascial patch as covering layers over urethral repair. To minimize the risk of urethral injury the tape is located on the side of the urethra at the 3 or 9 o'clock position and divided there.

The medial end of the divided tape is grasped with a short Allis clamp, lifted and peeled off the undersurface of the urethra from one side to the other. The lateral extensions of the mesh past the inferior edge of the pubic ramus toward the obturator fossa for total obturator tape or the upper arms of the tape extending toward the retropubic space for transvaginal tape are usually left intact to maintain some urethral support.

Urethrocystoscopy is repeated after suburethral tape removal to ensure that no urethral injury occurred and the urethral lumen returned to normal. Each removed segment is sent for pathology review for medicolegal documentation after being photographed.

For mesh removal the same method is used. As much mesh as possible is removed transvaginally whether it be anterior, posterior, apical, at some or at all of these locations, including the arms of these meshes extending as lateral as possible.

We analyzed the change in pain score between preoperative and postoperative visits, and used the last visit VAS score recorded in the electronic medical record. The Student t-test was used for statistical analysis with $p < 0.05$ considered significant.

RESULTS

From a database of 271 patients who underwent MTR during the study period we excluded 148, leaving 123 available for final analysis. Of the 148 excluded patients 92 had urinary obstruction/retention symptomatology, 87 had recurrent urinary tract infections, 42 had mesh extrusion, 4 underwent tape plus mesh removal at the same time and 11 had mesh erosion. Many women met more than 1 exclusion criterion. Of the 123 patients included on final analysis 69 and 54 underwent transvaginal mesh and suburethral tape removal, respectively. No patient had undergone a prior tape or mesh removal attempt.

Of the women 90% were white, 7% were Hispanic and 3% were black. Mean age at presentation was 52.8 years (range 38 to 72) and mean body mass index was 28 kg/m^2 (range 23 to 38). Mean time to presentation to our office since MTR surgery was 31 months (range 8 to 72). In the transvaginal mesh removal group the mesh was Avaulta® in 16% of cases, Prolift® in 39%, Perigee™ or Apogee™ in 9%, Elevate® in 21% and unspecified in the operative report in 15% (see table). The mean pain score preoperatively was 7.9 (range 5 to 10), which decreased to 0.9 (range 0 to 3) at a mean postoperative followup of 22 months (range 6 to 47) ($p = 0.0014$). In the suburethral tape removal group the

Demographics and pain outcome in women who underwent transvaginal mesh and suburethral tape removal for pain

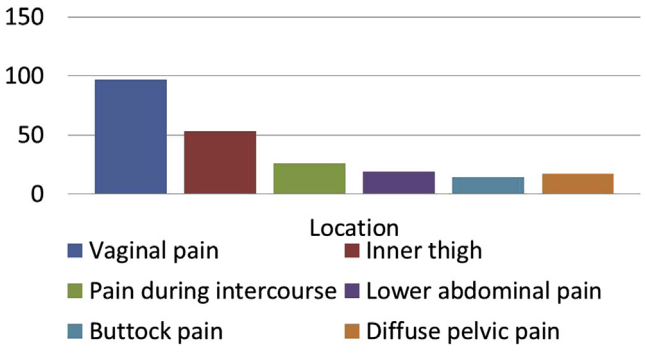
	Mesh		Tape		p Value
No. pts	69		54		
Mean age (range)	49 (41–63)		53 (38–72)		0.09
Mean kg/m^2 body mass index (range)	30 (23–38)		27 (24–36)		0.8
Mean placement-presentation interval (mos)	33 (10–68)		29 (8–72)		0.71
No. mesh type (%):		—		—	—
Prolift	27	(39)			
Elevate	14	(21)			
Avaulta	12	(16)			
Perigee/Apogee	6	(9)			
Unknown	10	(15)			
No. tape type (%):		—			—
Retropubic sling			26	(48)	
Transobturator sling			21	(39)	
Mini-sling			3	(5)	
Unknown			4	(8)	
Mean pain VAS score (range 0–10):					
Preop	7.9		5.3		0.068
Last postop visit	0.9		1.5		0.07
No. pain free (VAS 0)	46		44		—
No. persistent pain (no VAS change)	11		3		—

tape was a retropubic sling in 48% of cases, transobturator sling in 39%, mini-sling in 5% and unknown in 8%. The mean pain score preoperatively was 5.3 (range 4 to 8), which decreased to 1.5 (range 0 to 3) at a mean postoperative followup of 35 months (range 6 to 59) ($p = 0.00074$). Overall mean followup in the 2 groups was 28 months (see table).

There was a global VAS pain scale reduction of 5.1 points, demonstrating pain relief after transvaginal MTR. No intraoperative urethral, bladder or rectal injury was noted in this group of patients treated with MTR for pain only.

As reported by patients, pain site was classified as vaginal, inner thigh, lower abdominal or buttock pain and/or pain during intercourse. All patients described pain originating from more than 1 location. For mesh and tape the rate of vaginal pain predominated at 79% of cases (54 and 43), followed by 43% for inner thigh pain (20 and 33, respectively). The incidence of pain during intercourse was relatively low at 21% for mesh and tape (11 and 15 cases, respectively). This was because most patients with dyspareunia due to mesh or tape extrusion were excluded so that our study would focus only on pain symptomatology. Lower abdominal pain was noticed by 15% of patients (11 with mesh and 8 with tape) and buttock pain was noticed by 11% (12 and 2, respectively). In 14% of the patients (12 with mesh and 5 with tape) a component of diffuse pelvic pain was also reported. After MTR patients reported improvement in pain at these sites except for those with persistent pain. Of patients with persistent pain 64% (4 with mesh and 5 with tape) tended to report predominantly diffuse pelvic pain (see figure).

Pain-free status was achieved in 81% of patients after suburethral tape removal and in 67% after mesh removal. Six of the 14 patients with persistent pain elected conservative treatment with anti-inflammatory or local estrogen therapy while 4 and 2 elected treatment with physical therapists and pain specialists, respectively. Two patients were lost to followup after 6 months.



Vagina and inner thigh were most common pain sites reported by women.

Time from implantation to MTR was analyzed more specifically to evaluate its effect on pain relief. No statistically significant difference was noted in mean time to presentation after placement in the group with persistent pain vs overall mean time to presentation, including 36.2 months (range 31 to 42) vs 29 (range 8 to 72) for tape ($p = 0.0613$) and 37.5 months (range 32 to 39) vs 33 (range 10 to 68) for mesh ($p = 0.171$).

DISCUSSION

Postoperative pain has traditionally been difficult to treat. The classic dogma in surgery is not to operate for pain without an organic etiology. In this era of increasing transvaginal tape/mesh use physicians can expect to encounter patients who present with pelvic pain after transvaginal mesh or tape placement who do not have an organic etiology such as mesh erosion or extrusion. The rate of pelvic pain after transvaginal mesh or tape placement is difficult to estimate because various rates have been reported of different bothersome pelvic symptoms, including dyspareunia, obturator neuralgia and/or buttock pain. In series mentioning postoperative complications the rate of pelvic pain after transvaginal mesh or tape placement varies from 0% to 30%.[5,10–12]

Most of our patients reported more than 1 site of pain, consistent with other studies.[13,14] Vaginal and inner thigh pain were the most commonly reported sites of pain. Those investigators noted that several patients with a retropubic sling complained of groin/inner thigh pain. Although it was reported that transobturator MUS causes more inner thigh/groin pain than retropubic MUS, others documented that retropubic MUS can also cause significant inner thigh/groin pain.[15,16]

The exact mechanism and underlying pathophysiology of pain after transvaginal mesh or tape placement remain unclear. Svabik et al postulated mesh retraction possibly due technical error, resulting in mesh infolding and/or secondary mesh contraction caused by collagen deposition.[17] In a study of 103 women who underwent transvaginal ultrasound after mesh placement Rogowski et al found a significant correlation between mesh retraction and the severity of vaginal pain.[18] Other theories implicate excessive tension on tissues, possible muscle and/or nerve damage, irritation by the synthetic material or even subclinical infection.[3]

Excision of the suburethral MUS is usually sufficient to relieve obstructive symptoms while preserving some urethral support. However, for pain, especially when more localized to 1 side, vaginal removal of suburethral tape can require additional

excision of any segment that can be reached and tracked upward to the level of the pubic bone for retropubic MUS or laterally to the pubic ramus for transobturator MUS. It would be difficult to retrieve the ends of these tapes later. The decision to remove more sling material and even the entire sling is generally made later when pain persists suprapubically, or in the groin or inner thigh. At that point no more tape can be found beneath the urethra to the pubic bone and, thus, the remainder of any MUS segments must be accessed retropubically or translabially.

Determining etiology and treating pain after transvaginal mesh or tape placement is challenging for surgeons as well as patients. Often patients seek treatment for years by presenting to different specialists and exploring the potential benefits of conservative treatment for pain with anti-inflammatory drugs, local estrogen therapy, physical therapy and trigger point local injections.[19–22] In certain cases, such as those in our series, it may be necessary to consider mesh removal in the hope that it would decrease or eliminate the source of pain.[5,19]

However, little has been reported to date in support of this decision to remove mesh/tape for pain alone.[4] MTR can be complicated technically and fraught with additional complications due to urethral, bladder/ureter or rectal injury. In addition, the postoperative functional outcome regarding pain relief is not predictable, nor is the possibility of unmasking the symptoms that initially led to tape/mesh placement.[23–25]

In the current study from a tertiary care center we specifically excluded patients with other underlying complications such as erosion or extrusion. We analyzed the records of those who underwent MTR for pain as the primary reason for MTR. Many patients who presented with pain only after transvaginal mesh or tape placement and in whom conservative therapy had failed responded far better than expected to MTR based on the objective VAS outcome measure.

To our knowledge this is the largest series of patients studied for pain relief after MTR with midterm followup (mean 28 months). Prior studies of vaginal mesh or sling removal surgery for pain as the only and primary indication for intervention mention short-term followup in a small number of patients. In published data on pain outcomes after MTR surgery pain has been mixed with other surgical indications for removal, including mesh extrusion, mesh erosion, fistula and other complications of the transvaginal mesh/tape, confounding the evaluation of pain relief after MTR surgery.[4,13,26,27] To address this issue specifically we purposely excluded patients who had other indications for MTR.

MTR for pain alone is a reasonable indication to operate with safe, durable results. We recorded no intraoperative complication such as urethral, bladder or rectal injury, consistent with contemporary reports of mesh removal.[9] However, transvaginal MTR surgery is challenging and would be best performed at centers with sufficiently experienced surgeons.

This study has limitations, including the lack of information on implanting surgeon expertise, lack of a pain map to study pain sites, no prospective use of a validated sexual function tool and no available long-term data to study the possibility of recurrent pain symptomatology. Although the lack of a validated sexual questionnaire to evaluate dyspareunia is a limitation, this information is usually not collected at baseline before the tape or mesh is placed. When asked subsequently, recall bias would be unavoidable since many patients have not been sexually active for a while due to pain issues.

CONCLUSIONS

Persistent pelvic pain after transvaginal mesh or tape placement is a known complication. Our study indicates that pain alone after transvaginal mesh or tape placement can be a reasonable indication to perform removal surgery after conservative therapies fail. Many patients respond with symptomatic improvement and sometimes with even complete resolution of the original pain complaint(s).

ACKNOWLEDGMENTS

Dr. Ganesh Raj provided guidance and reviewed the manuscript.

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Int Urogynecol J (2015) 26:65–69
DOI 10.1007/s00192-014-2455-1

ORIGINAL ARTICLE

Postoperative pain outcomes after transvaginal mesh revision

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Received: 27 January 2014 / Accepted: 14 June 2014 / Published online: 11 July 2014

Abstract
Introduction and hypothesis Although the current literature discusses mesh complications including pain, as well as suggesting different techniques for removing mesh, there is little literature regarding pain outcomes after surgical removal or revision. The purpose of this study is to determine if surgical removal or revision of vaginal mesh improves patient's subjective complaints of pelvic pain associated with original placement of mesh.
Methods After obtaining approval from the Vanderbilt University Medical Center Institutional Review Board, a retrospective review of female patients with pain secondary to previous mesh placement who underwent excision or revision of vaginal mesh from January 2000 to August 2012 was performed. Patient age, relevant medical history including menopause status, previous hysterectomy, smoking status, and presence of diabetes, fibromyalgia, interstitial cystitis, and chronic pelvic pain, was obtained. Patients' postoperative pain complaints were assessed.
Results Of the 481 patients who underwent surgery for mesh revision, removal or urethrolysis, 233 patients met our inclusion criteria. One hundred and sixty-nine patients (73 %) reported that their pain improved, 19 (8 %) reported that their pain worsened, and 45 (19 %) reported that their pain remained unchanged after surgery. Prior history of chronic pelvic pain was associated with increased risk of failure of the procedure to relieve pain (OR 0.28, 95 % CI 0.12–0.64, p=0.003).
Conclusions Excision or revision of vaginal mesh appears to be effective in improving patients' pain symptoms most of the time. Patients with a history of chronic pelvic pain are at an increased risk of no improvement or of worsening pain.

Keywords Mesh · Pelvic pain · Mesh exposure · Mesh revision · Mesh excision

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Introduction

A US woman has an 11 % lifetime risk of undergoing surgery for urinary incontinence (UI) or pelvic organ prolapse (POP) by the age of 80 [1]. Since the introduction of vaginally placed synthetic mesh biomaterials (i.e., synthetic midurethral sling and transvaginal mesh prolapse systems or "mesh kits"), surgical treatment for UI and POP has changed dramatically over the past decade, marked by a rapid rise in the numbers of women treated [2]. In 2010, approximately 75,000 women underwent transvaginal mesh placement for POP and 210,000 for SUI [3]. Although these devices have improved outcomes [4], complications have also increased [5, 6], prompting the US Food and Drug Administration (FDA) to issue notifications regarding the safety and efficacy of polypropylene mesh used for pelvic organ prolapse [3]. Midurethral slings were omitted from this FDA warning and have been proven to be safe and efficacious for urinary incontinence. However, they are not without complications. An unfortunate, growing phenomenon facing all pelvic surgeons is the management of women with pelvic mesh complications, as this condition is multifaceted, complex, and challenging to treat.

Common complaints among patients with mesh complications are vaginal exposure, viscous perforations, infection, dyspareunia, partner pain, pelvic pain, and bladder pain [7]. The current published literature contains a myriad of studies describing the incidence and the management of most mesh

complications [8–10]; however, there are few data regarding pain outcomes after surgical removal or revision. Pain in particular is an increasingly common reason why women are seeking mesh removal. However, the prevalence of chronic pelvic pain in the general population is 12–20 % [11]. It is estimated that 850 per 100,000 patients self-report interstitial cystitis, and fibromyalgia prevalence is 2 %. With this knowledge that pain is a complicated process, the objective of our study is to determine if patients who have undergone surgical procedures for mesh complications have experienced improvement of their pain. The secondary objective is to determine if there are any underlying characteristics that might be predictive of worse outcomes after surgery for pain from vaginally placed mesh.

Materials and methods

After Vanderbilt University Medical Center Institutional Review Board (IRB) approval, a retrospective analysis was performed. Using CPT codes 53500, 57287, 57295, 57296, a database of all women who underwent vaginal mesh excision, revision or urethrolysis between January 2000 and August 2012 in two departments, Urology and Gynecology, was formed. Study data were collected and managed using REDCap electronic data capture tools hosted at Vanderbilt University [12].

Each patient encounter with the surgeon was evaluated. All visits that occurred prior to the mesh-revision surgery were reviewed for complaints of vaginal and/or pelvic pain. Patients were included in the study if the pain met two criteria: if the patient's pain began or worsened after placement of the mesh, and if the patient and/or provider attributed the pain to the mesh placement. The exclusion criterion was if the patient did not complain of pain prior to mesh excision or revision.

Once patients met the inclusion criteria, relevant demographic and medical data were extracted from the electronic medical record including: age; prior hysterectomy; menopause status; smoking history; diagnoses of diabetes, fibromyalgia, interstitial cystitis, and chronic pelvic pain; prerevision physical examination findings and intraoperative revision findings of any vagina exposure or bladder or urethral perforation. When available, original operative reports for mesh placement were reviewed. Mesh placement surgeries were categorized as the following: apical; bladder neck suspension; anterior; posterior; anterior and posterior; sling; sling and apical; sling and anterior; sling and posterior; and sling, anterior, and posterior.

The primary outcome was defined as the patient's perception of pain improvement after revision/removal. This was determined from the most recent follow-up visit to the surgeon and if he or she categorized the patient's pain as better, worse or unchanged. The total duration of postoperative follow-up was calculated from the most recent visit with any provider in the Urology or Gynecology departments.

Chi-squared or Fisher's exact test was used for descriptive comparisons. Multivariate logistic regression modeling was used to determine the associations between pain improvement (vs no change or worse) when taking into account each potential risk factor for pain, including menopause, hysterectomy, smoking status, presence of diabetes, fibromyalgia, interstitial cystitis, chronic pelvic pain, vaginal mesh exposure, bladder perforation or extrusion, and urethral perforation or extrusion. Statistical significance was defined as $p<0.05$. All analyses were performed using Stata 13.1 software.

Results

The original database collected 481 patients who underwent vaginal mesh revision, excision or urethrolysis. Of these 481 patients, 233 met our inclusion criteria of complaints of pain prior to mesh excision. Mean age of patient was 54 (range 23–89) and median follow-up was 12 months (range 1–120). The majority of these patients were postmenopausal (181, 78 %) and had undergone a prior hysterectomy (189, 81 %). Seventeen (7 %) patients reported a pre-existing history of fibromyalgia, 11 (5 %) of interstitial cystitis and 28 (12 %) of chronic pelvic pain before index mesh placement surgery (Table 1). Of the original mesh placement surgery, slings were placed in 187 patients (80 %), of whom 121 (65 %) had a sling only and the other 66 (35 %) had a concomitant prolapse procedure (Table 2). The mesh revision surgeries were all performed in the operating room. There were eight different providers during this time period performing these procedures. The majority of mesh excisions (209, 90 %) were performed transvaginally, and the remaining were completed abdominally (24, 10 %). Because several providers were involved, the methods of mesh revision or excision varied from minimal mesh revision to complete excision.

Overall, after mesh excision/revision surgery, 169 patients (73 %) reported improvement in pain, 45 (19 %) experienced no change in pain, and 19 (8 %) reported worsened pain (Table 1). There was no difference in improvement of pain if the mesh was removed vaginal or abdominally. Neither menopausal status nor hysterectomy predicted improvement in pain after mesh removal. Smoking and diabetes also showed an even distribution throughout the three outcome categories. However, in the pain syndromes, the chronic pelvic pain category had a smaller percentage in the improvement category than in the worsened and no change outcomes: 8 %, 26 %, and 22 % respectively.

One hundred and thirty-one (56 %) patients had mesh exposures: 103 (44 %) into the vagina, 14 (6 %) into the bladder, and 14 (6 %) into the urethra (Table 3). Overall, mesh excision improved pain in 101 patients with exposure (77 %),

Table 1 Cohort characteristics by pain outcome

	Total number	Pain improved, *n* (%)	Pain worsened, *n* (%)	Pain unchanged, *n* (%)	*p* value
All patients	233	169 (73)	19 (8)	45 (19)	
Mean age (54)		54.5	54.3	54.0	>0.05
Menopause	181	134 (79)	14 (74)	33 (73)	0.62
Prior hysterectomy	189	136 (80)	16 (84)	37 (82)	1.00
Current smoker	58	41 (24)	6 (32)	11 (24)	0.79
Diabetes	23	19 (11)	1 (5)	3 (7)	0.70
Fibromyalgia	17	9 (5)	3 (16)	5 (11)	0.10
Interstitial cystitis	11	6 (4)	1 (5)	4 (9)	0.26
Chronic pelvic pain	28	13 (8)	5 (26)	10 (22)	< 0.01

whereas 7 (5 %) reported no improvement and 23 (18 %) reported worse symptoms. Pain outcomes did not vary appreciably by location of exposure. However, compared with patients without exposure, those with exposure were more likely to be improved (77 % vs 67 %) and less likely to be worse after excision (5 % vs 12 %), although these differences were not statistically significant. Of the patients who had only sling placement, 77 % showed improvement, which is similar to those who had both SUI and POP mesh present.

Of all independent variables included in multivariate regression modeling, only chronic pelvic pain was predictive of pain outcomes in both univariate and multivariate regression models (Table 4). Patients with prior chronic pelvic pain were significantly less likely to experience improvement in pain symptoms (OR 0.28 CI: 0.12–0.66).

Discussion

In this large series, our findings demonstrate that the majority of patients who complain of pain after vaginal mesh placement will experience an improvement in their pain after surgical intervention. However, approximately 27 % of our patient population did not improve after surgical intervention, and of those, 8 % had worsening of their pain. From our patient population, all chronic pain disorders had odds ratios less than zero; however, chronic pelvic pain was the only subset that met statistical significance. This finding is consistent with other reports of patients with chronic pain syndromes, as patients who have chronic pain continue to have pain after other surgical interventions [13]. The ability to delineate the etiology of pain in this subset of patients is more difficult; therefore, pain that is attributed to synthetic mesh may not actually be related to the mesh. The pathophysiology of chronic pain may involve neuropathic changes that occurred before mesh was placed, which would prevent improvement after mesh removal [14].

Table 2 Location of initial mesh placement

	Total number, *n* (%)
Apical	19 (8)
Bladder neck suspension	4 (2)
Anterior repair	7 (3)
Posterior repair	3 (1)
Anterior/posterior repair	6 (3)
Sling	124 (53)
Sling and apical	15 (6)
Sling and anterior	34 (15)
Sling and posterior	6 (3)
Sling, anterior, posterior	15 (6)

Although there have been several publications on the complications of vaginal mesh and methods of removal, this is to our knowledge the first study that has specifically evaluated pain outcomes after mesh revision surgery. Because one of the main complaints and complications of vaginally placed mesh is some type of pain—pelvic, vaginal, lower extremity or dyspareunia—patients are asking for mesh removal, often with pain as the only symptom.

Although mesh has been used for hernia repair in different anatomical compartments for the past 30 years, it is a foreign body. There are known complications; however, the mechanism of the pain component has not yet been fully identified. Several case reports have been published recently theorizing the etiology of postoperative pain following mesh placement. Klein et al. described a patient who underwent umbilical hernia repair with mesh, who subsequently had chronic pain syndrome. Computed tomography (CT) examination was performed showing shrinkage, and at the time of surgical removal, adhesions to and inflammation around shrunken mesh were discovered. Pain completely resolved after removal of the mesh [15]. Irritation or injury of nerves has also been implicated in pain from these procedures. Fisher and Lotze described two patients with postoperative pain following

Table 3 Pain outcomes after mesh excision for patients with genitourinary mesh exposure/perforation

Site of mesh exposure/perforation	Total number (%)	Pain improved (%)	Pain worsened (%)	No change (%)	*p* value
Any exposure	131	101 (77)	7 (5)	23 (18)	0 .19
No exposure	102	68 (67)	12 (12)	22 (21)	
Location					
Vagina	103 (80)	78 (76)	5 (5)	20 (19)	0.28
Bladder	14 (10)	11 (79)	1 (7)	2 (14)	1.00
Urethra	14 (10)	12 (86)	1 (7)	1 (7)	0.52

retropubic sling procedures, both of whom had temporary resolution after local nerve blocks. One of these patients required complete sling excision for permanent improvement of pain [16]. Van Ba et al. reported obturator neuralgia and motor deficits after placement of vaginal mesh through obturator foramen for anterior vaginal prolapse. CT did not show neuroma or compression of neurovascular bundles. Surgical removal of mesh was completed without evidence of infection or neuroma; however, granulomatous tissue and evidence of inflammation around mesh were present. Complete resolution of symptoms occurred [17]. Another proposed mechanism for pain is mesh migration. While this is less documented in vaginal surgery, there have been several case reports of postoperative pain present in areas other than the location of original mesh placement. Imaging in these instances shows mesh not in the original site of placement but present in the areas of pain. Rarely, mesh has traveled great distances. For example, there is one report of a patient complaining of rectal pain after a ventral repair. Surgical exploration found mesh present in the rectum [18]. Therefore, although etiology is an important component, knowing when to operate on a patient to remove the mesh is also valuable. Removal and revision of vaginal mesh is often an extensive and potentially morbid procedure, and one that should not be performed unless necessary.

Strengths of this study include the large number of patients involved as well as the multiple providers spanning two departments. To our knowledge, this study represents the largest series of patients with pain outcomes after mesh removal. This allows for a sampling of several different surgical procedures for mesh removal or revision. This is the first study that has looked specifically at the pain component of mesh complications and correlated it with postoperative outcomes. The fact that our median follow-up time was a year is also a strength. Many of our patients were followed for longer periods and some for up to 3–4 years.

Because this is a retrospective study, there are several limitations. First, the definition for our pain outcome was limited to "improved, not improved or worse." We attempted to use a visual pain analog scale or some other measurement of pain symptoms. Because patients were seen by several different providers, a consistent evaluation of the pain was not possible. Data are also lacking on the other aspects of the patient's pain including location, character, duration, and quality. When deciding if a patient is a good candidate for surgery, these may be good predictors for success. We did not collect

Table 4 Unadjusted and adjusted odds ratios for risk factors predicting pain improvement after excision vs no improvement or worsening symptoms

Risk factor	Unadjusted OR (95 % CI)	*p* value	Adjusted OR (95 % CI)	*p* value
Age	1.02 (1.00–1.04)	0.11	1.01 (0.98–1.05)	0.37
Menopause	1.4 (0.71–2.70)	0.33	1.22 (0.50–2.99)	0.67
Hysterectomy	0.85 (0.40–1.82)	0.68	0.84 (0.37–1.96)	0.71
Smoking	0.89 (0.46–1.71)	0.71	1.05 (0.51–2.15)	0.89
Diabetes	1.9 (0.62–5.82)	0.26	1.58 (0.49–5.02)	0.44
Fibromyalgia	0.39 (0.14–1.07)	0.07	0.44 (0.15–1.33)	0.15
Interstitial cystitis	0.43 (0.13–1.48)	0.18	0.52 (0.14–1.94)	0.33
Chronic pelvic pain	0.27 (0.12–0.61)	<0.01	0.28 (0.12–0.66)	<0.01
Vaginal exposure	1.32 (0.74–2.38)	0.35	1.49 (0.78–2.86)	0.23
Bladder perforation	1.41 (0.38–5.21)	0.61	1.41 (0.36–5.52)	0.62
Urethral perforation	0.85 (0.40–1.82)	0.68	2.84 (0.57–14.25)	0.20
Any mesh exposure/perforation	1.54 (0.87 2.75)	0.14	1.53 (0.29–6.52)	0.69

data on the specific method of mesh revision or excision, which may also play a role in improvement. As there were several providers involved, the methods of excision and revision ranged from urethrolysis to partial excision and complete excision as well as different routes of surgery: vaginal versus urinary tract. The differing surgical approaches cause difficulty when attempting to draw conclusions regarding surgical intervention for mesh complications. To better understand if one method is superior to another, these would need a prospective evaluation.

While chronic pelvic pain was significant for worse outcomes, this patient population was small. In the same way, the other pain syndromes were small cohorts and could have reached statistical significance if the population were larger. In addition, the patients were placed into these groups because they had been given these diagnoses in their past medical history. Often diagnoses of these pain syndromes are made incorrectly, which would skew the data. Because the diagnosis was not standardized, there is a chance that some patients were misdiagnosed. There could also be patients who did have these diagnoses but were not placed in the category because the provider was not specifically looking for these syndromes.

Conclusion

Based on our study, the majority of the time when patients have pain that appears to be due to vaginal mesh placement, surgical intervention improves their pain. This may not be true in patients with chronic pelvic pain. This study is one of the first to delineate for which patients mesh revision surgery would be beneficial. Although our study showed less of an improvement in chronic pelvic pain, our methods may not be exact enough to see smaller increments of improvement. Using objective pain scales, descriptive pain terminology, and physical examination criteria would better categorize patient's pain and allow for a better understanding of the symptoms. Targeting appropriate candidates for surgery would theoretically decrease the number of patients for whom the surgery is not beneficial. This study is the initial step.

Conflicts of interest None.

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Reoperation 10 years after surgically managed pelvic organ prolapse and urinary incontinence

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OBJECTIVE: This study measured the 10-year risk of reoperation for surgically treated pelvic organ prolapse and urinary incontinence (POPUI) in a community population.

STUDY DESIGN: We conducted a prospective cohort analysis of 374 women who were > 20 years old and who underwent surgery for POPUI in 1995.

RESULTS: The 10-year reoperation rate was 17% by Kaplan Meier analysis. Previous POPUI surgery at the time of index surgery conferred a hazard ratio of 1.9 (95% CI, 1.1-3.2; $P = .018$). The abdominal approach was protective against reoperation compared with the vaginal approach (hazard ratio, 0.37; 95% CI, 0.17-0.83; $P = .02$) With the use of Cox regression, no association was observed for age, vaginal parity, previous hysterectomy, body mass index, prolapse severity, ethnicity, chronic lung disease, smoking, estrogen status, surgical indication, or anatomic compartment.

CONCLUSION: A reoperation rate of 17% is unacceptably high and likely represents an underestimate of the true rate. Most of the factors that influence reoperation have not yet been identified.

Key words: pelvic organ prolapse, surgery, urinary incontinence

Cite this article as: Denman MA, Gregory WT, Boyles SH, Smith V, Edwards SR, Clark AL. Reoperation 10 years after surgically managed pelvic organ prolapse and urinary incontinence. Am J Obstet Gynecol 2008;198:555.e1-555.e5.

Surgery for pelvic floor disorders is common. The lifetime risk of undergoing at least 1 surgery for either pelvic organ prolapse or urinary incontinence (POPUI) is reported to be 11.1%.[1] Reoperation is also common but not well quantified. In surgical trials from academic centers, the prevalence of previous POPUI surgery has been reported to be as high as 43%-56%. In a surgical cohort from a community-based population, the proportion of women with a history of POPUI surgery was 29%.[1-3]

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Presented at the 28th Annual Scientific Meeting of the American Urogynecologic Society, Hollywood, FL, Sept. 27-29, 2007.

Reprints not available from the authors.

0002-9378/$34.00

doi: 10.1016/j.ajog.2008.01.051

Reoperation implies, but is not synonymous with, surgical failure. Reoperation only represents patients who choose repeat surgery after failure of their initial surgery and does not reflect patients who choose nonsurgical or no additional therapy. The reoperation rate also includes those patients who experience a new problem after surgery (eg, new onset incontinence, development of prolapse in a different anatomic compartment). Reoperation may result from inherent risk factors for the development of prolapse or because prolapse repair in 1 compartment predisposes to new prolapse in another site.

The factors that influence the need for reoperation are not well understood. Many investigators believe certain factors for the development of POPUI itself may influence the success of a surgical repair. These factors include age, race, obesity, vaginal delivery, smoking, connective tissue disease, and hysterectomy. However, these factors have not been correlated with the need for reoperation.[4-8] Surgical technique, which includes approach, has also been implicated in failure, yet risk of reoperation was not studied.[9] Whether risk factors for reoperation are the same as those for the initial development of POPUI is not known.

Clark et al[10] reported on a 5-year cohort of community-based women who underwent POPUI surgery in 1995 and found that 13% of the women required reoperation during the 5-year time period. The only identified risk factor for repeat surgery was a history of POPUI surgery before the index surgery in 1995. In this study, the same cohort of women was followed for an additional 5 years. The objectives here were to determine the reoperation rate and to evaluate potential predictive factors for reoperation over a 10-year period.

Materials and Methods

A prospective cohort design was used. Institutional review board approval was obtained. Subjects were identified from 149,554 women who were >20 years old and who were members of Northwest Kaiser Permanente (KPNW) managed health care plan in 1995. The KPNW members were chosen because they are representative of the region's demographic and economic makeup. The ethnic composition of the cohort mirrors the ethnic composition of the KPNW membership. The population is 97.3%

white, 0.3% African American, 1.3% Asian, and 1.1% Hispanic. Additionally, electronic medical record usage and standardized intake forms allowed for ease of record review.

A total of 384 cases of POPUI surgery were identified in the 1995 cohort, 8 of which were repeat surgeries in that same year, which left a cohort of 376 women for long-term follow-up evaluation. The index surgeries that were performed in 1995 were identified by International Classification of Diseases–9th edition and Current Procedural Terminology codes and were confirmed by chart review.[1] The past medical, surgical, demographic, and lifestyle data were extracted from patients' charts at this time. Available variables hypothesized to be related to POPUI were recorded and included the patient's age at time of index surgery, their menopausal status and hormone use in 1995, smoking history, chronic lung disease, and chronic steroid use. Worst grade of prolapse before the surgery was recorded. Factors that were related to the surgery were also recorded and included the indication for surgery (prolapse, incontinence, or combination), the compartment(s) of surgery (anterior, posterior, apical), and the approach (vaginal, abdominal, both). Patients who underwent incontinence-only surgery (ie, retropubic suspension or sling procedure) were classified as having an anterior compartment procedure.

For the 10-year follow-up analysis, the medical record numbers of the original 376 subjects were used to identify subsequent POPUI surgeries by Current Procedural Terminology code for the 10-year period. The original database that was created from the 1995 cohort was used for factor analysis. KPNW registration data tracked subject departure from the cohort by membership data from the managed care system.

The primary outcome variable was repeat POPUI surgery in the 10-year time period.

Data were entered into a Filemaker database (Filemaker, Incorporated, Sunnydale, CA) that was designed for this study. Data analysis was performed with SPSS software (version 11.0: SPSS Inc, Chicago, IL). Kaplan Meier analysis curves were created to determine hazard ratios. Cox regression was used to test predictive factors against recurrent surgery. Surgical compartment of the index surgery was analyzed with the anterior compartment as a reference. Surgical approach was analyzed with the vaginal approach as the reference category. Cases were censored at the time of repeat surgery or at the time of loss to follow-up evaluation. A sensitivity analysis was performed with a model of different assumptions about those subjects who were lost to follow up.

Results

Of the 376 subjects who were identified initially as having undergone POPUI surgery in 1995, information regarding reoperation and/or departure from the KPNW system was available on 374 subjects. Subjects were followed for a mean of 92 ± 2.4 (SD) months. At the 10-year mark, 59% subjects (222/374) remained in the KPNW system. Yearly loss rate from the cohort averaged 4.8%, which was lower than the annual KPNW membership attrition rate of 16.2% during the same time period. Demographic data at the time of the index surgery on this group is summarized in Table 1.

During the 10-year time period, 55 women underwent repeat surgery. Of these, 9 women had 2 procedures during the 10-year time period. The small number of multiple reoperation subjects precluded analysis of risk for >1 reoperation during the 10-year time period. The type of procedure for the index cases and the repeat surgeries varied widely. These have been reported previously.[1,10] The most common sites for the index surgery were the anterior compartment and a combination of >1 site. The most common approach was vaginal (Table 1). For reoperations, the most common site was the anterior compartment (40%). Of the subjects who underwent reoperation, the most common approach was vaginal (83.3%).

At the 10-year mark, the overall reoperation rate by Kaplan-Meier survival analysis was 17%. Results of a univariate analysis of available variables are sum-

TABLE 1
Cohort characteristics at time of 1995 index surgery

Characteristic	Measure
Age (y)[a]	57.8 ± 13.4
Body mass index (kg/m^2)[a]	27.8 ± 5.6
Vaginal parity (n)[b]	3.0 ± 1.6
Hormone replacement therapy use (%)	81.5
Chronic lung disease (%)	22.2
Chronic steroid use (%)	3.2
Previous hysterectomy non-POP (%)	41.4
Race (%)	
White	95.5
Asian	1.1
Hispanic	1.3
African American	0.3
Unknown	1.8
Tobacco use (%)	
Never	58.8
Ever	23.6
Current	17.6
Surgery indication (%)	
POP	42
UI	35
POP+UI	23
Surgical approach (%)	
Vaginal	62
Abdominal	27
Combined	11
Surgical compartment (%)	
Anterior	33
Posterior	8
Apex	6
Anterior & posterior	16
Anterior & apex	16
Posterior & apex	4
All	17

[a] Data are given as mean ± SD.

[b] Data are given as median ± SD.

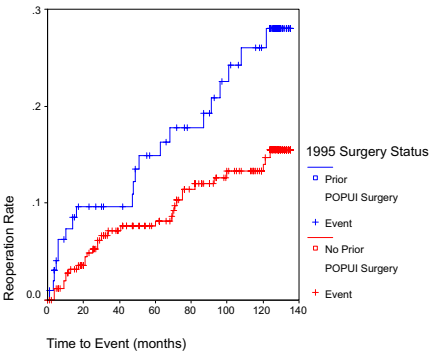
Denman. Reoperation 10 years after surgically managed pelvic organ prolapse and urinary incontinence. Am J Obstet Gynecol 2008.

TABLE 2
Univariate factor analysis on reoperation risk

Factor	Hazard ratio	CI	*P* value
Previous surgery	1.9	1.1-3.2	.018
Age	0.99	0.97-1.00	.26
Race	0.99	0.37-2.6	.98
Vaginal parity	0.96	0.81-1.15	.68
Menopausal status	0.81	0.46-1.44	.47
Hormone replacement therapy > 3 mo	1.44	0.65-3.2	.37
Smoking history	1.08	0.77-1.5	.65
Body mass index	1.01	0.97-1.06	.56
Chronic lung disease	0.71	0.33-1.51	.37
Chronic steroid use	0.05	0.0-43.9	.38
Hysterectomy for non-POP	1.05	0.61-1.79	.87
Worst grade of prolapse	1.02	0.8-1.28	.90
Indication for surgery			
POP	1	Reference	Reference
UI	0.90	0.49-1.64	.73
POPUI	0.85	0.42-1.73	.65
Compartment of initial surgery			
Anterior	1	Reference	Reference
Posterior	1.19	0.52-2.70	.69
Apex	1.32	0.40-4.37	.65
Anterior & posterior	2.03	0.66-6.21	.21
Anterior & apex	1.08	0.41-2.88	.88
Posterior & apex	0.80	0.28-2.32	.69
All	2.56	0.84-7.83	.10
Surgical approach			
Vaginal	Reference	Reference	Reference
Abdominal	0.37	0.17-0.83	.02
Combined	1.11	0.50-2.49	.79

Denman. Reoperation 10 years after surgically managed pelvic organ prolapse and urinary incontinence. Am J Obstet Gynecol 2008.

FIGURE 1
Reoperation risk by surgery status, 1995-2005



A comparison of reoperation rate for subjects with previous POPUI surgery (26%) with the rate for subjects with no previous surgery (14%) at the time of index surgery. Hazard ratio, 1.9; 95% CI, 1.1-3.2; $P = .02$.

Denman. Reoperation 10 years after surgically managed pelvic organ prolapse and urinary incontinence. Am J Obstet Gynecol 2008.

marized in Table 2. A history of POPUI surgery before the 1995 index surgery was associated significantly with reoperation. Of the 374 subjects in the cohort, 111 women had surgery before the index surgery in 1995; for the remaining 263 women, the index surgery was their initial POPUI surgery. With Kaplan-Meier survival analysis, 14% of the women (31/263) without previous POPUI surgery had a subsequent reoperation, whereas 26% of the women (24/111) with previous POPUI surgery had a subsequent reoperation during the 10-year period. This conferred a relative risk of 1.9 (95% CI, 1.1-3.2; $P = .02$; Figure 1)

Additionally, an abdominal approach was found to be protective (hazard ratio, 0.37; 95% CI, 0.17-0.83; $P = .02$), when compared with a vaginal approach to surgery. A combined approach was not found to impact the risk of reoperation, when compared with vaginal approach; but the number of cases was small.

No other factors were found to be significant predictors of reoperation. A multiple regression model that used factors with a probability value of <.2 (previous POPUI surgery, surgical approach, and compartment of surgery) conferred no statistically significant effect on the hazard ratios that were observed in the univariate model. With the multiple regression model, the reoperation risk (given a history of POPUI surgery before index surgery) was 1.8 (95% CI, 1.02-1.14; $P = .04$). With this model, the risk of reoperation with an abdominal approach at the time of the index surgery was 0.30 (95% CI, 0.12-0.74; $P = .01$). Surgical site had no effect on reoperation risk in the multiple regression model.

The number and variety of surgeries in the cohort limited the analysis of reoperation risk by surgery type. To attempt to differentiate between surgical failure as a cause for reoperation and de novo prolapse in another compartment, the site of the index surgery was compared with the site of the repeat surgery in the 55 subjects who had repeat surgery in the 10-year time period. Subjects with >1 POPUI surgery at the time of their index surgery were more likely to have same-site reoperations than subjects without a history of POPUI surgery before 1995, although the results did not reach statistical significance (Table 3).

Demographic data that were obtained at the time of the 1995 index surgery were

TABLE 3
Reoperation site compared with index 1995 surgery site

Reoperation	History of POPUI surgery at 1995 index surgery	No POPUI surgery before 1995 index surgery
Same site	71 (17/24)	39 (12/31)
Different site	29 (7/24)	61 (19/31)

Data are given as percentage (n/N); $P = .058$.

Denman. Reoperation 10 years after surgically managed pelvic organ prolapse and urinary incontinence. Am J Obstet Gynecol 2008.

compared between those women who left KPNW and those women who remained through the study period. No statistically significant differences between the 2 groups were found for a history of POPUI surgery, race, menopausal status, HRT use, previous non-POP hysterectomy, mean age, mean parity, or mean body mass index (Table 4). Mean follow-up period of women who left the KPNW system was 64 months (range, 1-130 months). Vaginal approach at index surgery was the same proportion in both groups (62%). Those women who remained at KPNW for the duration of the study had a higher percentage of reoperation (19% vs 9%; $P = .01$), when the data were compared with those women who left the KPNW before the end of the study period. Because of this difference, a sensitivity analysis was performed with the use of different assumptions about the population lost to follow-up evaluation. First, all patients who were lost to follow up were assumed to have undergone repeat surgery on the day they left KPNW system. In this scenario, the proportion of women with subsequent reoperation would be 51%. Second, assuming the population that left before reoperation (n = 144) had an equal rate of reoperation as those who remained in the cohort (17%), this would confer an additional 24 surgeries during the 10-year time period. With this assumption, the rate of reoperation is 21.1%.

Comment

In this population of women in the Pacific Northwest, women who undergo surgery for POPUI have a 17% rate of reoperation in the subsequent 10 years. This compares with our report of 13% after 5 years. As noted in our previous surveillance, a history of ≥ 1 POPUI surgery continues to confer an almost 2-fold risk of further POPUI surgery, when compared with the risk after an initial POPUI surgery.[10] In addition, an abdominal approach was found to be protective against future reoperation. This finding correlates well with previous studies that demonstrated decreased failure rates with an abdominal approach to prolapse surgery.[9,11] It is important to note that the effect of previous POPUI surgery procedures and surgical approach remained independent of the other test variables, including previous hysterectomy for nonprolapse indications.

The rate of reoperation that was measured in this cohort is likely to be an underestimate. Although the annual loss to follow up of 4.8% was small, this loss accumulated to 41% of the cohort over 10 years. The sensitivity analysis evaluates this potential influence. The reason for loss to follow up was not available and could include transfer of insurance or patient death. Also, women may have undergone repeat surgery elsewhere, while retaining KPNW membership. This would require full payment of all fees, which is a significant financial disincentive. We believe it highly unlikely that POPUI issues influence a subject's decision to remain in or depart from the cohort, and the true rate of reoperation is likely closer to 21%.

For women who had undergone previous POPUI surgery, reoperation was more likely to occur at the same anatomic site. In contrast, women who underwent reoperation after their first POPUI surgery were more likely to have surgery to address a different anatomic site. This trend implies a different pathophysiologic basis of failure for primary surgery vs repeated POPUI surgery.

Most factors that predict reoperation are likely variables that were not measured in this study. The primary mechanism of surgery, to restore anatomic structure of connective tissues, does not address neuromuscular dysfunction. In-

TABLE 4
Demographic comparison of patients who remained in KPNW for entire study period (1995-2005) with those patients who left the system before study completion

Variable	Left KPNW before 2005	Remained at KPNW	*P* value
History of POPUI surgery before 1995[a]	25 (39/153)	33 (72/221)	.17
White race[a]	94 (143/153)	97 (214/221)	.25
Menopausal status[a]	68 (104/152)	74 (161/219)	.17
Hormone replacement therapy use[a]	80 (120/151)	83 (176/212)	.24
Non-POP hysterectomy[a]	46 (70/153)	39 (85/221)	.16
Age (y)[b]	56.1	59.0	.05
Parity (n)[b]	3	3	.70
Body mass index (kg/m^2)[b]	28.1	27.7	.58

[a] Data are given as percentage (n/N).

[b] Data are given as mean.

Denman. Reoperation 10 years after surgically managed pelvic organ prolapse and urinary incontinence. Am J Obstet Gynecol 2008.

trinsic patient factors, such as pelvic floor muscle strength, genital hiatus size, or connective tissue quality, are not measured routinely and therefore are not available for analysis. Surgical techniques that included the use of mesh or graft material in the repair were also not available for review, although there was a significant protective effect of abdominal approach. Furthermore, detailed information regarding the POPUI surgeries before the 1995 index surgery was not available for comparative purposes. One of the limitations of this study that is applicable to most long-term surveillance studies is the rapidly changing nature of the surgeries and technology in the field of urogynecology.

Follow-up examinations were not available to evaluate the prevalence of recurrence, regardless of choice for reoperation. These factors would be beneficial in the determination of additional variables that may influence reoperation for POPUI surgery. Given that the rate of surgical failure is reported as high as 58%, there remains a significant number of patients with recurrent prolapse who do not seek further surgical correction.[12]

The advantages of this cohort included its generalizability and its extended time period of follow up. This cohort represents a large group of social and economically diverse white women in the northwestern United States, which allows extrapolation to similar populations nationwide. It represents the practice of an established urogynecology specialty clinic, with urogynecologists and general gynecologists providing care. Because the KPNW system is a managed care organization, there is no financial incentive or disincentive for surgeons toward repeat surgery.

A reoperation rate of 17% is unacceptably high and likely represents an underestimate of the true rate in the community setting. By comparison, reoperation rates for inguinal hernia range from 1.7%-4.3%.[13,14] However, POPUI presents a unique challenge for surgical repair compared with standard hernia surgery because of the often concomitant muscle and nerve damage that accompanies the anatomic defect. Moreover, most women need a procedure that will last 25-30 years, and the risk of reoperation is likely to continue to rise beyond this 10-year measure. The goal of more durable surgeries is clearly recognized in our field, as evidenced by the plethora of attempts to devise better surgical approaches. Long-term surveillance, although fraught with limitations and expense, is essential to monitor progress in attainment of that goal. ■

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Obturator Foramen Dissection for Excision of Symptomatic Transobturator Mesh

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Abbreviations and Acronyms

MUS = mid urethral sling

POP = pelvic organ prolapse

SUI = stress urinary incontinence

Submitted for publication August 26, 2011.

Study received institutional review board approval.

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† Nothing to disclose.

‡ Financial interest and/or other relationship with American Medical Systems, Ethicon Women's Health & Urology, Astellas, Cooper Surgical and E-Medsco.

§ Financial interest and/or other relationship with Allergan, Johnson & Johnson, Pfizer, Astellas, Serenity, Merck, Contura, Antares and Medtronic.

See Editorial on page 1529.

Editor's Note: This article is the fifth of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 1939 and 1940.

Purpose: Groin pain after transobturator synthetic mesh placement can be recalcitrant to conservative therapy and ultimately requires surgical excision. We describe our experiences with and technique of obturator foramen dissection for mesh excision.

Materials and Methods: The records of 8 patients treated from 2005 to 2010, were reviewed. Obturator dissection was performed via a lateral groin incision over the inferior pubic ramus at the level of the obturator foramen, typically in conjunction with orthopedic surgery.

Results: Five patients had transobturator mid urethral sling surgery for stress urinary incontinence, 2 had mid urethral sling and trocar based anterior vaginal wall mesh kits with transobturator passage of mesh arms for stress urinary incontinence and pelvic organ prolapse, and 1 had an anterior vaginal wall mesh kit for pelvic organ prolapse. Patients had 0 to 2 prior transvaginal mesh excisions before obturator surgery. All patients presented with intractable pain in the area of the obturator foramen and/or medial groin for which conservative treatment measures had failed. Six patients underwent concurrent vaginal and obturator dissection and 2 underwent obturator dissection alone. In all cases residual mesh (3 to 11 cm) was identified and excised from the obturator foramen. Mesh was closely associated to or traversing the adductor longus muscle and tendon with significant fibrous reaction in all cases. Postoperatively 5 patients were cured of pain and/or infection, and 3 reported no or some improvement at a mean followup of 6 months (range 1 to 12).

Conclusions: Our experience suggests that surgical excision of residual mesh can alleviate many of the symptoms in many patients. In all cases mesh remnants were identified and removed, and typically involved neuromuscular structures adjacent to the obturator foramen.

Key Words: surgical mesh; suburethral slings; obturator nerve; urinary incontinence, stress; pain

Groin pain after transobturator placement of pelvic mesh is a known complication of such procedures. Regardless of whether mesh is placed through the obturator foramen for SUI or POP, the occurrence of pain is typically localized to the inguinal area and medial thigh along the obturator nerve distribution. While not common, it is reported in up to 15% of patients undergoing transobturator MUS.[1–3] Typically the pain resolves with time, generally within a few weeks. Occasionally the pain is persistent, and

0022-5347/12/1875-1680/0
THE JOURNAL OF UROLOGY®

Vol. 187, 1680-1684, May 2012
Printed in U.S.A.
DOI:10.1016/j.juro.2011.12.065

requires treatment with oral analgesia, local injection of analgesia and steroids, or nerve block.[4,5] In a few instances the pain can be recalcitrant and devastating, and requires surgical excision to remove the offending material. We report on a series of patients with persistent symptoms from transobturator mesh who, after receiving optimized and exhaustive medical therapy, underwent obturator foramen dissection for mesh material excision.

MATERIALS AND METHODS

After obtaining institutional review board approval (#110917), a retrospective chart review was performed on patients who had undergone transobturator dissection for the excision of symptomatic mesh material at our institutions. Patients were identified from billing information and surgeon case logs. Demographic data, clinical information and intraoperative findings were abstracted from the medical records. The surgical technique is reviewed.

All the obturator dissections and mesh excisions were performed in the operating room with the patient under general anesthesia. Patients were placed in the dorsal lithotomy position, and the entire perineum and vulva, lower abdomen and medial thighs to the level of the knee were sterilely prepared and draped. Several patients underwent concurrent vaginal dissection and excision of mesh via a vaginal incision as well as an obturator dissection. Vaginal synthetic mesh material was generally identifiable visually or palpably, and this was dissected free from adjacent vaginal structures, and traced laterally to the level of the pubic ramus and obturator foramen. A variety of vaginal incisions and exposures were used for this portion of the procedure, although a midline or inverted U incision was used most commonly. In patients in whom a vaginal exploration had previously been performed, only the obturator dissection was performed in isolation.

Obturator dissection and mesh excision were performed through a lateral groin incision directly over the inferior pubic ramus at the level of the obturator foramen. Figure 1 depicts the anatomical structures of the inner thigh and obturator region. The incision was typically located 1 to 2 cm lateral to the pubic ramus and 3 to 4 cm inferior to the adductor longus tendon insertion (fig. 2). Using electrocautery and blunt dissection the incision was extended to the inferior pubic ramus on the medial aspect of the obturator foramen through the subcutaneous tissue and fat. The most superficial muscle overlying the foramen is the adductor brevis, which can be mobilized off the inferior pubic ramus by dividing its medial attachments to the bone and elevating it laterally to reveal the obturator externus muscle spanning the obturator foramen. Once identified, the pubic ramus was cleared of overlying tissue anteriorly and posteriorly around the medial aspect of the obturator foramen. If necessary to access palpable or visible mesh or to completely expose the obturator foramen when no mesh was identifiable, the gracilis muscle and tendon were also detached from its insertion medially to the obturator foramen.

In most cases mesh material was visible or palpable, and the dissection followed the course of the material. The mesh was dissected free of the surrounding tissue with a combination of sharp and blunt maneuvers. The obturator neurovascular structures were carefully identified and preserved when necessary, particularly if the mesh was in close proximity. If a vaginal excision of mesh had previously been performed, medial dissection of the mesh into or through the obturator foramen was generally limited. In those cases with concomitant vaginal dissection, mesh material was invariably identified vaginally and traced laterally to the obturator foramen. The obturator internus muscle, which overlies the medial or pelvic aspect of the obturator foramen, did not require specific dissection or mobilization in these instances. The mesh traversed this muscle through to the lateral obturator space.

In cases in which synthetic material was not immediately identified, the dissection was carried around the margin of the obturator foramen, preserving the neurovascular bundle exiting from the obturator canal in the superolateral aspect of the foramen. The obturator externus muscle and obturator membrane can also be dissected free and elevated to better expose the obturator foramen and canal, although this was not necessary in this series. The synthetic material was typically located more laterally and anteriorly than expected, often in close proximity to or traversing the adductor longus muscle.

Once the synthetic material was excised the incision was closed superficially after a closed suction drain was placed through a separate stab incision. Muscle and tendon structures were generally not reconstructed or repaired before closure.

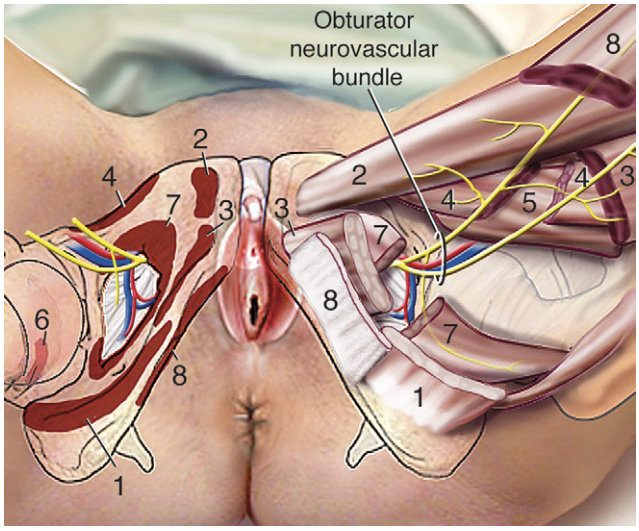

Figure 1. Illustration of inner thigh anatomy in region of obturator foramen: medial thigh muscles and attachments. 1, adductor magnus muscle. 2, adductor longus muscle. 3, adductor brevis muscle. 4, pectineus muscle. 5, iliopsoas muscle. 6, quadratus femoris muscle. 7, obturator externus muscle. 8, gracilis muscle. Reprinted with permission from Karram M and Pancholy A: Synthetic midurethral slings for the correction of stress incontinence. In: Atlas of Pelvic Anatomy and Gynecologic Surgery, 3rd edition. Edited by MS Baggish and MM Karram. St. Louis, Missouri: Elsevier-Saunders 2011; pp 747–780.

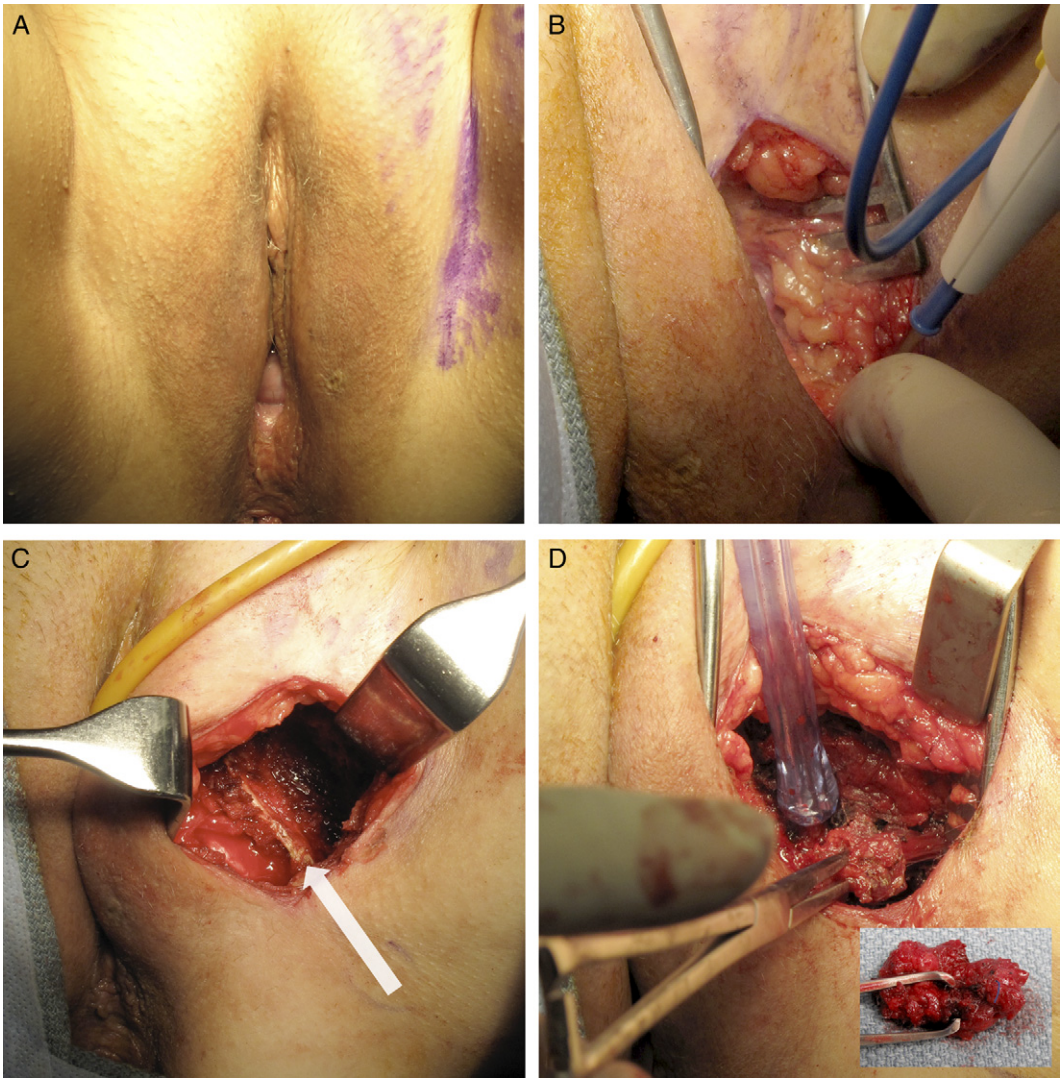

Figure 2. Surgical technique for obturator dissection and mesh excision. *A,* incision is made directly over inferior pubic ramus at level of obturator foramen. *B,* dissection extended down to pubic ramus. *C,* inferior pubic ramus (white arrow) and medial margin of obturator foramen can be cleared of overlying tissue. *D,* mesh is identified visually or palpably and excised (inset).

RESULTS

Between 2005 and 2010, 8 women with a mean age of 52 years (range 44 to 71) underwent obturator dissection for symptomatic transobturator mesh. All were referred to our practices from elsewhere after original placement of transobturator mesh. Five patients had undergone transobturator MUS surgery for SUI, 2 had received a transobturator MUS and a vaginal mesh kit with transobturator arms for SUI and POP, respectively, and 1 had vaginal mesh with transobturator arms placed for POP only. The specific type or brand of original transobturator procedure was not available, nor was the direction of trocar passage for mesh placement. Almost all patients (7 of 8) had undergone 1 to 2 previous transvaginal mesh excisions or explorations before undergoing obturator dissection, typically for the removal of symptomatic mesh, for exposed mesh in 2 patients, for pain in 2 and not reported for the remainder.

All patients presented with intractable pain in the area of the obturator foramen and/or medial groin and thigh. Oral analgesic therapy had failed, as had local analgesic injection and nerve block. Pain was on the right side in 3 patients, left side in 4 and bilateral in 1. Vaginal drainage and inguinal swelling was present in 1 woman, consistent with obturator canal infection.

At the obturator dissection 6 patients underwent concurrent vaginal and obturator dissection, while 2 had obturator dissection alone. The average interval between mesh placement and obturator surgery was 23.1 months (range 9 to 42). In all cases residual mesh was identified and excised from the obturator foramen as well as periobturator tissues and tendinous structures. Mesh was closely associated to or traversing the adductor longus

muscle and tendon insertion with significant fibrous reaction in all cases, and in 1 case the mesh was intimately associated with the obturator neurovascular bundle. Fragments of removed mesh ranged from 3 to 11 cm in length. The majority of mesh materials were Type 1 (macroporous, monofilament) polypropylene mesh, while 2 were specifically Obtape®, a Type II (microporous, monofilament) polypropylene mesh.

Postoperatively 5 (63%) patients were cured of pain and/or infection, while 3 had varying degrees of symptom improvement after transobturator mesh excision. Of these 3 patients 1 reported significant improvement initially with some pain recurrence, 1 reported mild improvement in site specific pain but no overall improvement in chronic pelvic pain and 1 has had no or minimal improvement. No patient reported new onset gait or hip range of motion impairment after surgery, although this issue was not specifically assessed at followup. In fact, most women experienced improvement in pain and were less encumbered with mobility issues after mesh removal. Mean followup was 6 months (range 1 to 12).

DISCUSSION

In this small, retrospective series of patients undergoing obturator dissection for symptomatic transobturator mesh excision of the offending material cured the majority (two-thirds) of women of the primary presenting symptom of pain. For the remainder of cases the procedure offered some improvement. In all cases we were able to identify and excise mesh material exiting the obturator foramen or in peri-obturator tissues. The mesh was usually located more laterally relative to the obturator foramen than expected from common placement techniques. Typically the mesh was directly investing or traversing the adductor longus muscle or tendon, or in close proximity to it, and it was usually accompanied by significant fibrous reaction and scarring.

Available data did not include much information on the initial placement of the transobturator mesh such as surgeon characteristics, type of transobturator kit used or direction of trocar passage. Therefore, it is difficult to draw conclusions related to aspects of transobturator mesh placement that may result in symptomatic mesh or in the need for transobturator dissection. Usually the transobturator trocar and mesh penetrate several muscles and structures of the inner thigh and pelvis, including (in order from external to internal) the gracilis muscle, adductor brevis muscle, obturator externus muscle, obturator membrane, obturator internus muscle and periurethral endopelvic connective tissue.[6,7] However, the adductor longus should be avoided.

Because of our intraoperative findings of mesh involving the adductor longus, we speculate that most of these complications were the result of technical errors, whereby the mesh was inserted too laterally, before (outside-in technique) or after (inside-out technique) traversing the obturator foramen. Cadaver studies evaluating the trajectories of transobturator trocar passage demonstrate wide variability in the courses the trocars follow, particularly in relation to the obturator canal and branches of the obturator nerve.[6–8] The trocar trajectories are also influenced by the positioning of the patients' legs during sling insertion, with increased hip flexion (at least 90 degrees or hyperflexion) associated with greater distance between trocar and obturator neurovascular structures.[8,9]

In our series women were more likely to undergo concurrent vaginal dissection early in our experience, when we were more concerned about locating the mesh exiting the obturator foramen or located in the groin structures. With experience we have more recently performed obturator dissection only, particularly in those cases in which a vaginal excision has already been performed. Additionally, we have typically reserved this procedure for select patients in whom more conservative therapies have failed, including oral and injection analgesic remedies. Others have reported success with these conservative measures.[3–5] Data on the number of patients treated with conservative measures, including the proportion of those with treatment failure who go on to obturator dissection, are not presently available from our series.

The use of synthetic mesh material for pelvic floor reconstruction, including SUI and POP, is widely popular. Many procedures use the transobturator route for mesh fixation. Groin pain develops in approximately 5% to 16% of patients treated for SUI[1,10] and in up to 4% of those treated for POP.[11] It almost always occurs after transobturator as opposed to retropubic sling surgery (odds ratio 8.05, 95% CI 3.78–7.16).[2] The pain is typically transient and generally resolves within a few weeks. Persistent groin pain is rare and uncommonly reported.[3–5,12] Groin pain after transobturator procedures is believed to be related to obturator nerve damage or entrapment and to resulting neuropathy.[4,13] In addition, it may be nonneural in origin, and related to tension between the mesh material and adductor tissues.[4] Risk factors for groin/leg pain are not well elucidated, but leg positioning at implantation[9] and normal body mass index (compared to obese)[1] have been reported as possible risks.

We have previously described our initial results with 1 patient requiring this procedure to remove painful mesh.[12] That patient has also been included in this series. Encouraged by the success of that initial patient, we have offered obturator dissection to additional patients as described in this study. We initially recommend conservative treatments with oral analgesia as well as injection therapy, and will surgically address any obvious abnormality with the

vaginal portion of the mesh such as mesh exposure, obstruction or hyper-suspension. Pelvic pain after mid urethral sling surgery (retropubic and transobturator) can improve with vaginal excision or lysis of mesh material alone in two-thirds of patients.[14] In some instances laparoscopic removal of retropubic mesh was effective for obturator pain after retropubic mid urethral sling surgery.[15] Candidates for obturator dissection are typically those women with persistent pain at the obturator foramen or medial thigh after these other measures have failed.

The timing of definitive mesh excision in this series was delayed, averaging almost 2 years after mesh placement. This reflects the inherent difficulties in effectively treating this clinical condition, where definitive treatment is often delayed by conservative measures and vaginal mesh excisions. Some authors have suggested that earlier removal of symptomatic mesh is better than delayed removal because the risk of scarring is less and permanent nerve damage is avoided.[5] A formal analysis of time to mesh removal and clinical outcomes was not performed due to the limited number of cases. However, those patients treated less than 24 months after mesh improvement all had complete resolution of symptoms (4), while those treated after 24 months had mixed outcomes (resolution in 1, persistent pain in 3). Nevertheless, it is imprudent to draw specific conclusions from so few patients.

The small number of patients included in this study precludes wide-ranging recommendations for the management of this difficult clinical situation. We have provided a general description of the surgical technique we use for this procedure. However, we certainly acknowledge that much is uncertain in terms of the finer aspects of the surgery. For example, as described, we typically have not reattached or reconstructed muscle and tendon structures divided during dissection. We have not found any obvious limitation to this, but we do not know if it will be an important aspect for future function.

In addition, this study is hampered by the retrospective nature as documentation and quantification of pain levels and locations were not standardized nor prospectively assessed, and by the relatively short postoperative followup. However, anecdotally, surgical excision for symptomatic transobturator mesh is performed occasionally by a number of physicians. To our knowledge, this represents the largest series of patients described having undergone this procedure as well as the most descriptive report of the surgical approach and technique.

CONCLUSIONS

Our collective experience with intractable groin and obturator pain after transobturator synthetic mesh placement suggests that surgical excision of residual mesh can alleviate most of the symptoms in many patients. In this series more than half of the patients were cured of their pain and symptoms, while the remainder mostly experienced improvement. In all cases mesh remnants were identified and removed, typically from inadvertently involved neuromuscular structures adjacent to the obturator foramen.

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Current trends in surgical repair of pelvic organ prolapse

Lisa Rogo-Gupta

Purpose of review
Over the past decade, surgical prolapse correction has evolved significantly, taking a sharp turn in 2011 when the USFDA publicly questioned synthetic graft safety. This controversy has been widely publicized and debated amongst laymen and experts alike. This review summarizes current trends in mesh implantation for prolapse repair, highlighting the impact of the current controversy.

Recent findings
Recent studies revealed nonmesh prolapse repair may have better outcomes than previously reported; the USFDA states there is insufficient evidence to support vaginal mesh for apical or posterior compartment prolapse; mesh prolapse repair increased over the past decade, 75% of which was placed vaginally; approximately 30% of mesh prolapse repair is performed with hysterectomy and approximately 40% is performed with concomitant incontinence repair. Anterior and apical prolapse are most likely to include mesh and of apical repair procedures, minimally invasive approaches exceed laparotomy.

Summary
This year's population-based studies describe the impact of surgeon experience, prolapse compartment, and national trends in surgical technique on mesh prolapse repair. The impact of the recent investigation on future mesh use remains unknown.

Keywords
incontinence, mesh, pelvic organ prolapse, surgery

INTRODUCTION

The surgical management of pelvic organ prolapse (POP) has evolved significantly over the past decades with the popularization of minimally invasive surgery and the widespread adoption of grafts into pelvic reconstructive surgery. This evolution took a sharp turn in 2011 when the safety of synthetic grafts, also referred to as 'mesh,' came into question by the USFDA, a controversy that has been widely publicized and debated amongst laymen and experts alike. The purpose of this review is to describe the current trends in mesh implantation for POP repair, highlighting the impact of the current controversy.

EPIDEMIOLOGY OF PELVIC FLOOR DISORDERS

Epidemiological studies of pelvic floor disorders (PFDs) place them amongst the most common chronic illnesses, affecting 24% of US women [1]. Prolapse may be asymptomatic in up to half of cases [2] with the remainder reporting bothersome symptoms of pelvic fullness and vaginal discomfort. The majority of prolapse is treated nonsurgically; however women carry an 11% lifetime risk of undergoing surgical correction [3].

Risk factors for PFDs have been identified. First, age is the most significant risk factor with 10% of women ages 20–39 years suffering from one or more PFD compared with 50% of those 80 years and older [1]. Second, pregnancy and delivery are associated with prolapse, however even nulliparous women are at risk [4]. Third, racial differences in prolapse incidence have been identified with Hispanic women at highest risk for uterine prolapse and African–American women at lowest risk for prolapse overall

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Curr Opin Obstet Gynecol 2013, 25:395–398
DOI:10.1097/GCO.0b013e3283648cfb

KEY POINTS

- Nonmesh prolapse repair may have higher subjective success and lower reoperation rates than previously reported.
- The USFDA states there is insufficient evidence to support vaginal mesh for apical or posterior compartment prolapse, and there is no demonstrated difference in subjective outcomes for mesh anterior compartment repair compared with traditional repairs.
- Mesh implantation for POP correction increased over the past decade and 75% were placed vaginally.
- Anterior and apical compartment POP were most likely to be repaired with mesh over the past decade and among apical POP repaired abdominally, laparoscopic and robotic sacrocolpopexy have outnumbered laparotomy since 2009.
- The USFDA investigation into POP mesh is ongoing and its impact on future trends remains unknown.

[5]. Finally, lifestyle factors including obesity and smoking increase the risk of prolapse and serve as important points of intervention to prevent development of PFDs [6].

TRENDS IN SURGICAL PELVIC ORGAN PROLAPSE CORRECTION

Recent technological advancements promote evolution in surgical prolapse management. First, these advancements shift how prolapse surgery is performed. Historically prolapse procedures were most often performed by inpatient laparotomy and included hysterectomy until the mid 1990s when minimally invasive ambulatory procedures gained widespread popularity [7]. The introduction of robotic assistance to traditional laparoscopic sacrocolpopexy has certainly contributed to this rise in minimally invasive procedures since 2005 and current literature suggests the trend towards an increase in laparoscopic and robotic sacrocolpopexy will continue [8▪▪,9]. Minimally invasive procedures also reduce hospital cost, offering an additional incentive over laparotomy [10].

Single-institution cohort studies and case series with short-term outcomes provide the majority of the literature comparing sacrocolpopexy approach. Recent longer term follow-up data of these cohorts has so far suggested traditional open abdominal sacrocolpopexy may have comparable anatomic outcomes to the minimally invasive approaches [11,12]. Anatomic outcomes also appear comparable between traditional laparoscopic and robotic-assisted techniques [13].

Advancements have also been made in prolapse repair materials. Traditional vaginal repair techniques involve plicating weakened areas with local tissue. Although these procedures are generally considered to be minimally invasive and well tolerated by patients, initial outcomes studies reported high lifetime failure risks [14]. Other biologic tissue such as cadaveric and porcine grafts, autologous rectus fascia and fascia lata have been used in vaginal prolapse repair however they do not significantly improve outcomes compared with traditional repair [15].

MESH IN PELVIC ORGAN PROLAPSE CORRECTION

The failure of biologic grafts to significantly improve prolapse repair outcomes over traditional repairs contributed to the rapid increase in recent use of synthetic products [16]. Surgical mesh was cleared by the USFDA for UI repair in 1996 and for POP repair in 2001 [17] and since approval multiple products have been introduced with modifications in shape, composition, and attachment method [18].

Early enthusiasm for mesh-augmented prolapse repairs was followed by cautionary advisories from multiple organizations worldwide. Systematic reviews cited a lack of reliable evidence to support unrestricted mesh POP repair while new techniques were introduced faster than could be evaluated with good quality evidence [15,16,19–22]. The USFDA released two publications regarding mesh complications, a Public Health Notification in 2008 followed by a Safety Warning in 2011 [23]. They stated there is insufficient evidence to support vaginal mesh for apical or posterior compartment prolapse, and there is no demonstrated difference in subjective outcomes for mesh anterior compartment repair compared with traditional repair.

Mesh data remains difficult to interpret due to lack of standardization in both methods and outcome measures. For example, a recent single-center randomized control trial comparing mesh and nonmesh POP repairs found similar subjective outcomes and lower objective failure rates than previously reported, with a 20% mesh exposure rate at 1 year in posthysterectomy patients [24]. A single-center international cohort study of a single mesh product demonstrated over 90% success, many of whom underwent concurrent hysterectomy or sling [25], while a multicenter international cohort study of a different product reported 70% success with 10% exposure rate at 2 years [26].

Surgical outcome measures are also evolving and patient satisfaction is increasingly used as an adjunct to objective outcome. When subjective success is measured, success rates of anterior POP repair from randomized control trials rise to 62–100% with reoperation rates of 5–9%, considerably lower than previous estimates [27]. Additional literature demonstrates more encouraging longer-term outcomes and some experts promote this new perspective on nonmesh repairs [28].

Mesh complications impact trends in mesh use, however accurate estimation of complication rate is challenging. Large retrospective cohorts report reoperation rates as low as 1.3% for urinary complications and less than 1% for erosion [29] while others report erosion and dyspareunia occur in up to 30–40% [30].

Sexual function after prolapse repair varies. Sexually active women undergoing prolapse repairs should be counseled regarding the risk of dyspareunia postoperatively although long-term sexual satisfaction may improve [31–34]. Patients should also be aware that unrepaired prolapse and nonmesh repairs are also risk factors for decreased sexual satisfaction [35].

NATIONAL TRENDS

National trends in mesh use for surgical POP repair were relatively unknown until publication of two population-based studies this past year describing an overall rise in mesh use with differences in trends depending on multiple patient and physician factors [8▪▪,36▪]. Previous estimates of mesh use relied on industry sales and estimated one-third of POP procedures included mesh, 75% of which were placed vaginally, which totaled approximately 75 000 cases in 2010 [23].

The first of these studies describes national trends in prolapse mesh use from 2000 to 2010 and different trends between the prolapsed compartments. The key points of the national trends in mesh POP repair, 2000–2010 are as follows [36▪]:

(1) Mesh prolapse repair increased overall, most dramatically from 2000–2006.
(2) Predictors of mesh use include UI and age over 50 years. Nonwhite women and those who undergo hysterectomy are less likely to undergo a mesh repair.
(3) Anterior and apical prolapse is repaired with mesh more often than posterior and multiple compartment prolapse.
(4) The highest volume surgeons are most likely to use mesh although their use has declined since 2008.
(5) Gynecologists gradually adopted mesh and perform more prolapse repairs overall while urologists rapidly adopted mesh and are more likely to use it compared with gynecologists.

In this cohort, 43% underwent concomitant UI procedure and 23–33% of those who received mesh underwent hysterectomy.

The second population-based study described trends in prolapse mesh use from 2005 to 2010, highlighting the differences between mesh placed vaginally compared with abdominally. The key points of the national trends in mesh POP repair approaches, 2005–2010 are as follows [8▪▪]:

(1) Seventy-five percent of mesh prolapse repair is performed vaginally.
(2) Vaginal mesh prolapse repair increased over time, most dramatically from 2005 to 2008.
(3) Vaginal repair is the most common prolapse repair approach across all age groups.
(4) Abdominal sacrocolpopexy was more common than laparoscopic and robotic-assisted approaches; however minimally invasive procedures dramatically increased after 2007 and exceeded the abdominal approach in 2009 and 2010.
(5) Half of vaginal and minimally invasive prolapse repairs are performed as outpatient procedures.

In this cohort, 40% underwent concomitant sling and 27% concomitant hysterectomy.

CONCLUSION

In conclusion, recent literature adds valuable information to the current controversy of mesh in POP correction. We knew the factors impacting the decision to incorporate mesh on an individual patient, however this year's population-based studies revealed the impact of surgeon experience, prolapse compartment, and surgical technique on national trends. Recent literature also demonstrates more encouraging longer term outcomes for nonmesh repairs and increased risks associated with mesh.

The impact of the current controversy on future mesh use remains unknown. Pelvic surgeons are now faced with the difficult task of formulating a unified opinion regarding the future role of mesh in POP repair based on high-quality evidence and carefully selected outcome measures [37–39].

Acknowledgements

None.

Conflicts of interest

None to disclose.

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- ■ of special interest
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